

JS 44 (Rev. 06/17)

**CIVIL COVER SHEET**

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)

**I. (a) PLAINTIFFS**

Sigmapharm Laboratories, LLC

(b) County of Residence of First Listed Plaintiff Bucks

(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys (Firm Name, Address, and Telephone Number)  
Henry F. Siedzikowski, Esquire and Timothy T. Myers, Esquire  
ELLIOTT GREENLEAF, P.C., 925 Harvest Drive, Suite 200,  
Blue Bell, PA 19422, (215) 977-1000

**DEFENDANTS**

Rising Pharmaceuticals, Inc. and Aceto Corporation

County of Residence of First Listed Defendant Bergen

(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys (If Known)

**II. BASIS OF JURISDICTION** (Place an "X" in One Box Only)

- ☐ 1 U.S. Government Plaintiff
- ☐ 2 U.S. Government Defendant
- ☐ 3 Federal Question (U.S. Government Not a Party)
- ☒ 4 Diversity (Indicate Citizenship of Parties in Item III)

**III. CITIZENSHIP OF PRINCIPAL PARTIES** (Place an "X" in One Box for Plaintiff and One Box for Defendant)

- |   | PTF                        | DEF                        |   | PTF                                   | DEF                                   |
|---|----------------------------|----------------------------|---|---------------------------------------|---------------------------------------|
| Citizen of This State                   | <input type="checkbox"/> 1 | <input type="checkbox"/> 1 | Incorporated or Principal Place of Business In This State     | <input checked="" type="checkbox"/> 4 | <input type="checkbox"/> 4            |
| Citizen of Another State                | <input type="checkbox"/> 2 | <input type="checkbox"/> 2 | Incorporated and Principal Place of Business In Another State | <input type="checkbox"/> 5            | <input checked="" type="checkbox"/> 5 |
| Citizen or Subject of a Foreign Country | <input type="checkbox"/> 3 | <input type="checkbox"/> 3 | Foreign Nation  | <input type="checkbox"/> 6            | <input type="checkbox"/> 6            |

**IV. NATURE OF SUIT** (Place an "X" in One Box Only)

Click here for: Nature of Suit Code Descriptions.

CONTRACT	TORTS	FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES
<input type="checkbox"/> 110 Insurance <input type="checkbox"/> 120 Marine <input type="checkbox"/> 130 Miller Act <input type="checkbox"/> 140 Negotiable Instrument <input type="checkbox"/> 150 Recovery of Overpayment & Enforcement of Judgment <input type="checkbox"/> 151 Medicare Act <input type="checkbox"/> 152 Recovery of Defaulted Student Loans (Excludes Veterans) <input type="checkbox"/> 153 Recovery of Overpayment of Veteran's Benefits <input type="checkbox"/> 160 Stockholders' Suits <input checked="" type="checkbox"/> 190 Other Contract <input type="checkbox"/> 195 Contract Product Liability <input type="checkbox"/> 196 Franchise	<b>PERSONAL INJURY</b> <input type="checkbox"/> 310 Airplane <input type="checkbox"/> 315 Airplane Product Liability <input type="checkbox"/> 320 Assault, Libel & Slander <input type="checkbox"/> 330 Federal Employers' Liability <input type="checkbox"/> 340 Marine <input type="checkbox"/> 345 Marine Product Liability <input type="checkbox"/> 350 Motor Vehicle <input type="checkbox"/> 355 Motor Vehicle Product Liability <input type="checkbox"/> 360 Other Personal Injury <input type="checkbox"/> 362 Personal Injury - Medical Malpractice	<b>PERSONAL INJURY</b> <input type="checkbox"/> 365 Personal Injury - Product Liability <input type="checkbox"/> 367 Health Care/Pharmaceutical Personal Injury Product Liability <input type="checkbox"/> 368 Asbestos Personal Injury Product Liability <b>PERSONAL PROPERTY</b> <input type="checkbox"/> 370 Other Fraud <input type="checkbox"/> 371 Truth in Lending <input type="checkbox"/> 380 Other Personal Property Damage <input type="checkbox"/> 385 Property Damage Product Liability	<input type="checkbox"/> 625 Drug Related Seizure of Property 21 USC 881 <input type="checkbox"/> 690 Other	<input type="checkbox"/> 422 Appeal 28 USC 158 <input type="checkbox"/> 423 Withdrawal 28 USC 157 <b>PROPERTY RIGHTS</b> <input type="checkbox"/> 820 Copyrights <input type="checkbox"/> 830 Patent <input type="checkbox"/> 835 Patent - Abbreviated New Drug Application <input type="checkbox"/> 840 Trademark
<b>REAL PROPERTY</b> <input type="checkbox"/> 210 Land Condemnation <input type="checkbox"/> 220 Foreclosure <input type="checkbox"/> 230 Rent Lease & Ejectment <input type="checkbox"/> 240 Torts to Land <input type="checkbox"/> 245 Tort Product Liability <input type="checkbox"/> 290 All Other Real Property	<b>CIVIL RIGHTS</b> <input type="checkbox"/> 440 Other Civil Rights <input type="checkbox"/> 441 Voting <input type="checkbox"/> 442 Employment <input type="checkbox"/> 443 Housing/Accommodations <input type="checkbox"/> 445 Amer. w/Disabilities - Employment <input type="checkbox"/> 446 Amer. w/Disabilities - Other <input type="checkbox"/> 448 Education	<b>PRISONER PETITIONS</b> <b>Habeas Corpus:</b> <input type="checkbox"/> 463 Alien Detainee <input type="checkbox"/> 510 Motions to Vacate Sentence <input type="checkbox"/> 530 General <input type="checkbox"/> 535 Death Penalty <b>Other:</b> <input type="checkbox"/> 540 Mandamus & Other <input type="checkbox"/> 550 Civil Rights <input type="checkbox"/> 555 Prison Condition <input type="checkbox"/> 560 Civil Detainee - Conditions of Confinement	<b>LABOR</b> <input type="checkbox"/> 710 Fair Labor Standards Act <input type="checkbox"/> 720 Labor/Management Relations <input type="checkbox"/> 740 Railway Labor Act <input type="checkbox"/> 751 Family and Medical Leave Act <input type="checkbox"/> 790 Other Labor Litigation <input type="checkbox"/> 791 Employee Retirement Income Security Act	<input type="checkbox"/> 375 False Claims Act <input type="checkbox"/> 376 Qui Tam (31 USC 3729(a)) <input type="checkbox"/> 400 State Reapportionment <input type="checkbox"/> 410 Antitrust <input type="checkbox"/> 430 Banks and Banking <input type="checkbox"/> 450 Commerce <input type="checkbox"/> 460 Deportation <input type="checkbox"/> 470 Racketeer Influenced and Corrupt Organizations <input type="checkbox"/> 480 Consumer Credit <input type="checkbox"/> 490 Cable/Sat TV <input type="checkbox"/> 850 Securities/Commodities/Exchange <input type="checkbox"/> 890 Other Statutory Actions <input type="checkbox"/> 891 Agricultural Acts <input type="checkbox"/> 893 Environmental Matters <input type="checkbox"/> 895 Freedom of Information Act <input type="checkbox"/> 896 Arbitration <input type="checkbox"/> 899 Administrative Procedure Act/Review or Appeal of Agency Decision <input type="checkbox"/> 950 Constitutionality of State Statutes
			<b>SOCIAL SECURITY</b> <input type="checkbox"/> 861 HIA (1395ff) <input type="checkbox"/> 862 Black Lung (923) <input type="checkbox"/> 863 DIWC/DIWW (405(g)) <input type="checkbox"/> 864 SSID Title XVI <input type="checkbox"/> 865 RSI (405(g))	<b>FEDERAL TAX SUITS</b> <input type="checkbox"/> 870 Taxes (U.S. Plaintiff or Defendant) <input type="checkbox"/> 871 IRS—Third Party 26 USC 7609
		<b>IMMIGRATION</b> <input type="checkbox"/> 462 Naturalization Application <input type="checkbox"/> 465 Other Immigration Actions		

**V. ORIGIN** (Place an "X" in One Box Only)

- ☒ 1 Original Proceeding
- ☐ 2 Removed from State Court
- ☐ 3 Remanded from Appellate Court
- ☐ 4 Reinstated or Reopened
- ☐ 5 Transferred from Another District (specify)
- ☐ 6 Multidistrict Litigation - Transfer
- ☐ 8 Multidistrict Litigation - Direct File

**VI. CAUSE OF ACTION**

Cite the U.S. Civil Statute under which you are filing (Do not cite jurisdictional statutes unless diversity):

28 U.S.C. § 2201

Brief description of cause:

Declaratory and Injunctive Relief; breach of contract and fraud

**VII. REQUESTED IN COMPLAINT:**
☐ CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, F.R.Cv.P.
**DEMAND \$**

CHECK YES only if demanded in complaint:

**JURY DEMAND:** ☒ Yes ☐ No**VIII. RELATED CASE(S) IF ANY**

(See instructions):

JUDGE

DOCKET NUMBER

DATE

03/22/2018

SIGNATURE OF ATTORNEY OF RECORD

FOR OFFICE USE ONLY

RECEIPT #

AMOUNT

APPLYING IFP

JUDGE

MAG. JUDGE

## UNITED STATES DISTRICT COURT

FOR THE EASTERN DISTRICT OF PENNSYLVANIA — DESIGNATION FORM to be used by counsel to indicate the category of the case for the purpose of assignment to appropriate calendar.

Address of Plaintiff: 3375 Progress Drive, Bensalem, PA 19020

Address of Defendant: Rising - 250 Pehle Ave., Suite 601, Saddle Brook, NJ 07663 and

Place of Accident, Incident or Transaction: Aceto - 4 Tri Harbor Ct., Port Washington, NY 11050

(Use Reverse Side For Additional Space)

Does this civil action involve a nongovernmental corporate party with any parent corporation and any publicly held corporation owning 10% or more of its stock?

(Attach two copies of the Disclosure Statement Form in accordance with Fed.R.Civ.P. 7.1(a))

Yes ☐ No ☒

Does this case involve multidistrict litigation possibilities?

Yes ☐ No ☒

RELATED CASE, IF ANY:

Case Number: \_\_\_\_\_ Judge \_\_\_\_\_ Date Terminated: \_\_\_\_\_

Civil cases are deemed related when yes is answered to any of the following questions:

1. Is this case related to property included in an earlier numbered suit pending or within one year previously terminated action in this court?  
Yes ☐ No ☒
2. Does this case involve the same issue of fact or grow out of the same transaction as a prior suit pending or within one year previously terminated action in this court?  
Yes ☐ No ☒
3. Does this case involve the validity or infringement of a patent already in suit or any earlier numbered case pending or within one year previously terminated action in this court?  
Yes ☐ No ☒
4. Is this case a second or successive habeas corpus, social security appeal, or pro se civil rights case filed by the same individual?  
Yes ☐ No ☒

CIVIL: (Place ☒ in ONE CATEGORY ONLY)

A. Federal Question Cases:

1. ☐ Indemnity Contract, Marine Contract, and All Other Contracts
2. ☐ FELA
3. ☐ Jones Act-Personal Injury
4. ☐ Antitrust
5. ☐ Patent
6. ☐ Labor-Management Relations
7. ☐ Civil Rights
8. ☐ Habeas Corpus
9. ☐ Securities Act(s) Cases
10. ☐ Social Security Review Cases
11. ☐ All other Federal Question Cases  
(Please specify) \_\_\_\_\_

B. Diversity Jurisdiction Cases:

1. ☐ Insurance Contract and Other Contracts
2. ☐ Airplane Personal Injury
3. ☐ Assault, Defamation
4. ☐ Marine Personal Injury
5. ☐ Motor Vehicle Personal Injury
6. ☐ Other Personal Injury (Please specify)
7. ☐ Products Liability
8. ☐ Products Liability — Asbestos
9. ☒ All other Diversity Cases

(Please specify) Declaratory Action  
28 U.S.C. § 2201

ARBITRATION CERTIFICATION

(Check Appropriate Category)

I, Timothy T. Myers,

counsel of record do hereby certify:

☒ Pursuant to Local Civil Rule 53.2, Section 3(c)(2), that to the best of my knowledge and belief, the damages recoverable in this civil action case exceed the sum of \$150,000.00 exclusive of interest and costs;

☒ Relief other than monetary damages is sought.

DATE: 03/22/2018

Timothy T. Myers

#46959

Attorney-at-Law

Attorney I.D.#

NOTE: A trial de novo will be a trial by jury only if there has been compliance with F.R.C.P. 38.

I certify that, to my knowledge, the within case is not related to any case now pending or within one year previously terminated action in this court except as noted above.

DATE: 03/22/2018

Timothy T. Myers

#46959

Attorney-at-Law

Attorney I.D.#

**IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

**CASE MANAGEMENT TRACK DESIGNATION FORM**

Sigmapharm Laboratories, LLC	:	CIVIL ACTION
	:	
v.	:	
	:	
Rising Pharmaceuticals, Inc. and	:	NO.
Aceto Corporation	:	


In accordance with the Civil Justice Expense and Delay Reduction Plan of this court, counsel for plaintiff shall complete a Case Management Track Designation Form in all civil cases at the time of filing the complaint and serve a copy on all defendants. (See § 1:03 of the plan set forth on the reverse side of this form.) In the event that a defendant does not agree with the plaintiff regarding said designation, that defendant shall, with its first appearance, submit to the clerk of court and serve on the plaintiff and all other parties, a Case Management Track Designation Form specifying the track to which that defendant believes the case should be assigned.

**SELECT ONE OF THE FOLLOWING CASE MANAGEMENT TRACKS:**

- (a) Habeas Corpus – Cases brought under 28 U.S.C. § 2241 through § 2255. ( )
- (b) Social Security – Cases requesting review of a decision of the Secretary of Health and Human Services denying plaintiff Social Security Benefits. ( )
- (c) Arbitration – Cases required to be designated for arbitration under Local Civil Rule 53.2. ( )
- (d) Asbestos – Cases involving claims for personal injury or property damage from exposure to asbestos. ( )
- (e) Special Management – Cases that do not fall into tracks (a) through (d) that are commonly referred to as complex and that need special or intense management by the court. (See reverse side of this form for a detailed explanation of special management cases.) ( )
- (f) Standard Management – Cases that do not fall into any one of the other tracks. (x)

03/22/2018

**Date**

  
Timothy T. Myers, Esq.  
**Attorney-at-law**

Sigmapharm Laboratories, LLC  
**Attorney for Plaintiff**

(215) 977-1000

**Telephone**

(215) 977-1099

**FAX Number**

ttm@elliottgreenleaf.com

**E-Mail Address**

**UNITED STATES DISTRICT COURT FOR  
THE EASTERN DISTRICT OF PENNSYLVANIA**

**SIGMAPHARM LABORATORIES, LLC:**

**3375 Progress Drive :**

**Bensalem, PA 19020 :**

**v. :**

**RISING PHARMACEUTICALS, INC. :**

**Park 80 West – Plaza I :**

**250 Pehle Avenue, Suite 601 :**

**Saddle Brook, NJ 07663 :**

**and :**

**ACETO CORPORATION :**

**4 Tri Harbor Court :**

**Port Washington, NY 11050**

**CIVIL ACTION NO. \_\_\_\_\_**

**JURY TRIAL DEMANDED**

**CIVIL ACTION COMPLAINT**

Plaintiff, Sigmapharm Laboratories, LLC, by its undersigned attorneys, hereby files this Complaint against Defendants, Rising Pharmaceuticals, Inc. and Aceto Corporation, for declaratory and injunctive relief, breach of contract, promissory estoppel/detrimental reliance, unjust enrichment/quantum meruit, and fraud, and alleges as follows:

**THE PARTIES**

1. Plaintiff, Sigmapharm Laboratories, LLC (“Sigmapharm”) is a Pennsylvania Limited Liability Company with its principal place of business at 3375 Progress Drive, Bensalem, PA 19020. Sigmapharm is and was at all relevant times engaged in the business of developing, marketing, licensing, manufacturing and otherwise commercializing innovative pharmaceutical technologies and products.

2. Defendant Rising Pharmaceuticals, Inc. (“Rising”) is a New Jersey corporation currently having its principal place of business at Park 80 West – Plaza I, 250 Pehle Avenue, Suite 601, Saddle Brook, NJ 07663, and is currently a wholly owned subsidiary of Defendant Aceto Corporation, and presently conducts, and did at all relevant times conduct, substantial

business in Pennsylvania, including as more fully described in this Complaint.

3. Defendant Aceto Corporation (“Aceto”) is a publicly traded company, with its principal place of business at 4 Tri Harbor Court, Port Washington, NY 11050. Like Rising, Aceto presently conducts, and did at all relevant times conduct, substantial business in Pennsylvania, including as more fully described in this Complaint.<sup>1</sup>

### **JURISDICTION AND VENUE**

4. Jurisdiction exists pursuant to 28 U.S.C. §1332 (diversity of jurisdiction). The matter in controversy and the value of the relief sought herein exceeds \$150,000, exclusive of interest or costs.

5. Venue in this Court is proper. All parties do substantial business in the State of Pennsylvania. Plaintiff Sigmapharm’s principal place of business is in Bensalem, Pennsylvania. As set forth below, Defendants Rising and Aceto repeatedly met with, conducted and transacted business with Plaintiff Sigmapharm at its offices and facilities located in Bensalem, Pennsylvania.

### **FACTUAL BACKGROUND**

#### **The Development And Collaboration Agreement**

6. Sigmapharm has expertise in, and technology relating to, the development and manufacture of solid dosage form pharmaceutical products. Sigmapharm also has substantial experience in obtaining regulatory approval for such pharmaceutical products. In addition, Sigmapharm has substantial experience in manufacturing such products for commercial use, and in marketing, distributing and selling such pharmaceutical products in the United States.

7. In June 2006, Sigmapharm signed a Master Product Development and Collaboration Agreement (the “Agreement”) with Defendant Rising. A copy of the Agreement

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<sup>1</sup> Defendants Rising and Aceto may be also denoted together herein as “Rising-Aceto.”

is attached hereto as Exhibit “1.”

8. Pursuant to the Agreement, the parties agreed to collaborate in order for Sigmapharm to develop and obtain regulatory approvals for certain selected and agreed upon generic pharmaceutical products by filing for each of such products an Abbreviated New Drug Application (“ANDA”), and, once developed and approved by the U.S. Food and Drug Administration (the “FDA”), Sigmapharm would manufacture such pharmaceuticals for commercial use (the “Sigmapharm Products”) and Rising would exclusively market and distribute them in the United States.<sup>2</sup>

9. Pursuant to the Agreement, Sigmapharm is the ANDA holder of all Sigmapharm Products subject to this action.

10. Under Section 7 of the Agreement, Sigmapharm granted Rising an exclusive license (even as to Sigmapharm) to market and distribute the Sigmapharm Products in the United States. Therefore, Sigmapharm would manufacture all of the Sigmapharm Products and Rising would exclusively market and distribute them.

11. In exchange for the right to be the exclusive distributor of Sigmapharm Products, Rising pays Sigmapharm certain license fees equal to 55% of Net Profits. These payments are outlined in Section 8.3 of the Agreement and the corresponding Schedule for each Sigmapharm Product:

**8.3. Distribution of Net Profits.** Within forty-five (45) days after the end of each Calendar Quarter, Rising shall calculate the Net Sales and the Net Profits obtained from the sale of Products during such Calendar Quarter and shall distribute to Sigmapharm, Sigmapharm’s Percentage of such Net Profits. Rising shall supply Sigmapharm with a written report setting forth the Net Sales and Net Profits during such Calendar Quarter. If Net Profits related to a Product for any Calendar Quarter is negative, then either Party

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<sup>2</sup> A “generic” drug is a drug product that is comparable to a brand/reference listed drug product in dosage form, strength, quality and performance characteristics, and intended use.

may invoice the other Party for such amount due to it in accordance with this Agreement and in proportion to each Party's Percentage of such quarterly loss. Such payment shall be made within thirty (30) days of such invoice.

12. Under Section 2.1.2 of the Agreement, Rising is responsible for all sales and marketing activities of the Sigmapharm Products, and is required to consult "on a regular basis" with Sigmapharm on, *inter alia*, all marketing and sales efforts, and any instituted price changes associated with the Sigmapharm Products by Rising.

13. Rising also represented to and assured Sigmapharm that it possessed all required knowledge and expertise in exercising Commercially Reasonable Efforts to form effective and profitable marketing, pricing and distribution plans for the sale of the Sigmapharm Products ("Marketing Services").

14. Rising further represented and warranted that it possessed all required knowledge and expertise to perform in good faith: (a) all Marketing Services; and (b) administrative tasks associated with the distribution of the Sigmapharm Products ensuring a **transparent** business relationship between the two parties ("Distribution Services").

15. In return for the Marketing and Distribution Services, Rising initially received the fee described in Section 1.52 of the Agreement ("Rising's Fee") calculated based on Net Sales.

16. The Agreement originally applied to just one generic pharmaceutical drug product, Amiloride Hydrochloride. Other drug products were added in 2008 (i.e., Ergocalciferol, Protriptyline Hydrochloride and Disulfiram) and again in 2010 (i.e., Flucytosine, Griseofulvin Microsized and Griseofulvin Ultramicrosized).

17. On September 4, 2008, the parties amended Section 1.52 of the Agreement to calculate Rising's Fee to be on a per product basis (i.e., based on the quarterly Net Sales of each Sigmapharm Product).

18. Under the terms of the Agreement, within forty-five (45) days after the end of each certain calendar quarter, Rising would account to Sigmapharm for gross sales invoiced by Rising during such certain calendar quarter, which were adjusted to take into account certain deductions for discounts, chargebacks, rebates, returns and miscellaneous credits (collectively referred to herein as “Sales Expenses”) that had been paid by Rising during that certain calendar quarter, to reach Net Sales. From there, the parties to the Agreement would deduct a Cost of Goods (“COGs”) and a fee for Rising to reach a Net Profit on a cash basis.

19. This fee for Rising, which is identified as Rising’s Fee (*see* §1.52 of the Agreement), and comprised of the two elements: Product Distribution (i.e., Distribution Services) and Marketing and Sales, (i.e., Marketing Services), includes, but is not limited to, rebate and chargeback management, accounting, and marketing/sales administration and is calculated as a percentage of Net Sales, ranging over the years from 6% to 8% of Net Sales.

20. The Agreement requires Rising to pay 55% of the Net Profit to Sigmapharm and retain 45% for itself.

21. Rising is required under the terms of the Agreement to maintain all of the original source documents for the accounting to be “transparent” and subject to audit by Sigmapharm.

22. Section 1.37 of the Agreement states in part:

1.37. ...Subject to **Section 8.6** below, all deductions listed in the above articles (1.36 and 1.37) **shall be transparent** and readily available for independent audit purposes. (Emphasis added.)

23. Section 8.6 of the Agreement states in part:

8.6. Maintenance of Record; Audits. During the term of this Agreement and for a period of at least seven (7) years after the date of termination of this Agreement, each Party shall keep complete and accurate records of all expenses incurred by it under this Agreement, which expenses are to be reimbursed by one or both of the other Parties....



**Aceto's Acquisition Of Rising**

24. In 2010, Defendant Aceto acquired Defendant Rising.

25. On December 20, 2010, Rising informed Sigmapharm that Sun Acquisition Corp., a wholly owned subsidiary of Defendant Aceto, acquired substantial Rising assets. In the same letter, Rising represented to Sigmapharm that Sun Acquisition Corp. would change its name to Rising Pharmaceutical, Inc.

26. However, Section 14.1 of the Agreement states that “[n]either Party may sell, assign, pledge, hypothecate or otherwise dispose of its interests under this Agreement without the consent of the other Party....”

27. Rising-Aceto requested Sigmapharm’s consent for the assignment of the Agreement from the “old Rising” (i.e., the original Rising entity that entered into the Agreement) to the “new Rising” owned by Aceto (i.e., the Defendants in this complaint).

28. As a condition for Sigmapharm’s consent, Rising represented and warranted acceptance of all its obligations under the Agreement (hereinafter “Assignment”), a copy of which is attached hereto as Exhibit “2.”

29. Rising-Aceto represented that they would abide by their obligations under the Agreement in good faith, and Plaintiff reasonably believed and relied on Rising-Aceto doing so. Rising-Aceto’s representations and warranties induced Sigmapharm to consent to the Assignment.

30. Prior to, and after January 6, 2011, (the date of the Assignment) to the present, Sigmapharm has timely and faithfully performed and continues to perform its obligations under the Agreement.

31. Rising-Aceto, however, breached their obligations and duties concerning

transparency, reporting and open access to their books and records, and the calculation and payment of their Rising Fee.

**Rising-Aceto's Concealment Of Their Flawed  
And Fraudulent Accounting And Massive Underpayments**

32. The Rising Fee received by Rising-Aceto from 2009 to date is approximately \$11.5 Million Dollars, divided between the fees for Marketing and Distribution Services.

33. In the Proforma Profit Statement reports from Rising-Aceto for the calendar quarter ending December 31, 2014 (i.e., Q4-14), Sigmapharm noticed a large increase in chargebacks and rebates (which are part of Sales Expenses), but there did not appear to be any market explanation for this increase.

34. Specifically, Sigmapharm noticed two new categories of "actual" Sales Expenses entitled: *"Rebates and Admin Fees in house and in process"* and *"Chargebacks – In House 12/31 pending processing."* No market explanation was provided justifying these two new categories added by Rising-Aceto or supporting these additional Sales Expenses, which drastically reduced Net Sales by almost \$3 million or 44%, and to which Sigmapharm never agreed.

35. Since these additional new Sales Expenses introduced by Rising-Aceto were apparently accrued Sales Expenses (not actual cash based expenses), Sigmapharm's Richard Kremer, Vice President of Finance, agreed in the beginning of 2015 with his counterpart at Rising-Aceto, Vice President of Finance, Peter Licata, to obtain Rising-Aceto's relevant future profit sharing reports on both cash and accrual bases. While the Agreement required the accounting and payments to be on a cash basis, Sigmapharm agreed that Rising-Aceto would also provide their accrual accounting, which, as a subsidiary of Aceto, a publicly traded company, Rising was required to keep by Generally Accepted Accounting Principles ("GAAP").

36. Indeed, on May 4, 2015, starting from the first calendar quarter of 2015 (Q1-15), Rising began providing its quarterly profit statements to Sigmapharm with the relevant profit share payment information calculated on both cash and accrual bases. The payment made by Rising to Sigmapharm was supposed to continue to be stemming from the purported “transparent,” “cash basis” accounting as required by the Agreement.

37. At a face-to-face meeting at Sigmapharm’s offices in Bensalem, Pennsylvania between representatives of Sigmapharm’s and Rising-Aceto’s management teams on November 20, 2015, and in accordance with Section 8.3 of the Agreement, Sigmapharm requested an audit of the profit share figures reported by Rising-Aceto from 2009 through Q4-15. Sigmapharm followed up in writing on December 4, 2015, and requested Rising-Aceto to provide all relevant product information, back-up support and cash basis accounting for the predecessor Rising’s and now-merged Rising-Aceto’s quarterly calculations of the Net Profits and Net Sales for the years 2009 through 2015, in order for Sigmapharm to prepare for such audit.

38. On March 18, 2016 and after more than 4 months and numerous follow-up requests, only part of the information requested for this audit was sent by Rising-Aceto as historical data in electronic format. Sigmapharm realized that the information received was incomplete because significant data fields were missing from the requested information. As a result, on the same day received, Sigmapharm communicated this problem to Rising’s Finance Supervisor, Ms. Leslie Thomas, and requested the missing information initially requested on December 4, 2015. After no response from Rising-Aceto, Sigmapharm again communicated this problem four days later on March 22, 2016, to Mr. Peter Licata, the Vice President of Finance, and Mr. Scott Elian, the Controller, of Rising.

39. Despite frequent and persistent attempts during the following months of 2016,

Sigmapharm never received the type of complete accurate information it requested on December 4, 2015, to prepare for its audit, which in the meantime was expanded to also include Q1-16.

40. Sigmapharm has stated to Rising-Aceto on multiple occasions that this type of situation was absolutely unacceptable, especially in view of the fact that Rising-Aceto were consistently receiving as per the Agreement a 6% to 8% cut of the Net Sales of each quarter in order to be thoroughly organizing and maintaining on a transparent cash basis all product distribution and financial records of the Sigmapharm Products marketed, sold and distributed exclusively by Rising-Aceto in the United States market.

41. After numerous verbal and written requests from Sigmapharm to receive complete information for its audit, from December 2015 to December 2016, and while Rising-Aceto were slowly trickling out parts of this requested information, continuously withdrawing and revising parts of previously presented data, or delaying and confusing the data collection process, and, based on the fact that no further information was provided by Rising after September 16, 2016, Sigmapharm formally summarized its findings in the form of a notice of breach, audit letter and invoices to be paid by Rising for money still owed to Sigmapharm from the audit period starting from the 2009 inception through Q1-16.

42. During this period of time, Rising intentionally deployed a strategy designed to confuse the collection of the relevant data and provide fragmented batches of information to Sigmapharm.

43. Moreover, a short period after such disclosures, and following questioning by Sigmapharm, Rising told Sigmapharm to disregard parts of the disclosed information and then it submitted revised data.

44. By way of example, on September 1, 2016, Sigmapharm demanded that Rising

disclose the requested information by October 17, 2016.

45. After Rising failed to respond, Sigmapharm informed it that "... Sigmapharm would have to assume that no support exists for the items in question and determine the true Net Sales for profit share calculation based on this assumption."

46. The same day, Rising's Vice President, Peter Licata, responded that additional information supporting Rising's calculation of Net Sales and Net Profits existed. Yet, to this day, Rising has refused and failed to provide this information.

47. Relying solely on the data provided by Rising, Sigmapharm discovered multiple material breaches of the Agreement by Rising.

**Rising-Aceto Failed To Cure Material Breaches**

48. On December 16, 2016, Sigmapharm notified Rising of Rising's material breaches of the Agreement, including the following:

- i. Underpayment of Net Profits from Q2-2009 to Q1-2016 in the amount of \$1,905,110.38 (this underpayment practice of Rising continues to date);
- ii. Improper recordings and calculations of Cash Discounts and Medicaid rebates charged by Rising;
- iii. Improper calculation of Cost of Goods resulting in underpayment of \$1,109,491.81 by Rising to Sigmapharm (the miscalculation of Cost of Goods continues to date);
- iv. Charges to Sigmapharm for damaged Sigmapharm Products during shipment to a customer for which, on information and belief, Rising received a reimbursement; and
- v. Failure to pay Sigmapharm's invoice dated August 19, 2015.

49. In the meantime, while the painful efforts to obtain the correct and complete contractually mandated information requested for its audit were continuing to be made throughout 2016, Sigmapharm continued to supply Rising-Aceto all relevant Sigmapharm Products ordered by them for distribution, marketing and sale in the United States.

50. Rising-Aceto kept sending to Sigmapharm, although sometimes delayed, quarterly summary accounting reports and cash-based profit share payments for Q2-16, Q3-16 and Q4-16.

51. No profit share payment was made to Sigmapharm for Q1-17, which was due on or before May 15, 2017, since, according to Rising-Aceto's accounting, the cash based Net Profits were purportedly negative \$971,465 for that quarter.

52. Section 8.3 of the Agreement states in part:

8.3. ... If Net Profit related to a Product for any Calendar Quarter is negative, then either Party may invoice the other Party for such amount due to it in accordance with this Agreement and in proportion to each Party's Percentage for such quarterly loss. ...

53. Rising-Aceto never invoiced Sigmapharm its corresponding negative \$534,306 share for this quarterly loss, thereby evidencing their knowledge that the profit share accounting calculations and figures reported to Sigmapharm were not correct.

54. However, Sigmapharm noticed in the accounting statements for each of those quarters (i.e., Q2-16, Q3-16, Q4-16 and Q1-17) that all of the accrued Sales Expenses (i.e., the total sum of the related chargebacks, rebates, returns, allowances, etc.) were negative for each quarter.

55. Specifically, the accrued Sales Expenses for Q2-16, Q3-16, Q4-16 and Q1-17 were reported by Rising-Aceto as minus (-) \$804,304, \$2,438,874, \$2,321,960 and \$3,860,077, respectively, for an inconceivable 4-quarter cumulative negative accrual of Sales Expenses equal

to minus (-) \$9,425,216.

56. As set forth above, the cash based profit share accounting report for Q1-17, received by Sigmapharm on April 19, 2017, included yet another negative accrual of over \$3.86 million. At that time, Sigmapharm realized that there must be a serious problem with Rising-Aceto's reporting of accrued Sales Expenses. This, along with Sigmapharm having received no response to its December 16, 2016 notice of breach, caused Sigmapharm to insist on an emergency meeting with Rising-Aceto.

57. For five (5) months, Rising-Aceto ignored Sigmapharm's notices of material breaches to the Agreement.

**The May 23, 2017 Meeting And Rising-Aceto's Continued Delay And Concealment**

58. Finally, Rising-Aceto's Chief Operating Officer, Walter Kaczmarek, and Vice President of Strategic Planning and Development, Rajiv Hazaray, agreed to meet on May 23, 2017, with Sigmapharm's Chairman and Chief Executive Officer, Dr. Spiro Spireas and its Vice President of Finance, Richard Kremer.

59. During the May 23, 2017 meeting at Sigmapharm's offices, Rising-Aceto admitted that customer requests for credits, which should be part of accrued Sales Expenses (since they had not been paid yet), and not actual credit memos that are the truly made cash based payments of Rising-Aceto for such requested customer credits, could have been included in the reporting of the actual cash based Sales Expenses. Rising-Aceto further theorized that the corresponding actual credit memos issued to satisfy such customer credit requests would also be included in Rising-Aceto's reporting of actual Sales Expenses. Such double counting in the actual, cash based Sales Expenses would have explained why accrued Sales Expenses reporting would be negative.

60. In response to Sigmapharm's questioning of why Rising-Aceto would include such unpaid customer credit requests in their cash based profit share accounting for Sigmapharm, a situation clearly against the terms of transparency and cash based accounting required by the Agreement, Rising-Aceto's Vice President Hazaray curiously responded that this was a common practice of past Rising-Aceto's managements, and that he and his colleagues were currently working as the new management team to address all those discrepancies.

61. In fact, the new Rising-Aceto management team in the room on May 23, 2017 went on to say that previous management teams of Rising and Aceto were using two "buckets" to put expenses and treat them differently depending on various factors including the "specific needs" of certain projects and agreements.

62. Furthermore, the new Rising-Aceto management team assured Sigmapharm that they would immediately: (a) look into, and respond to, the missing accounting information requested by Sigmapharm since December 2015 and the unanswered notice of breach, audit letter and unpaid audit invoices sent to Rising on December 16, 2016; (b) follow up on Sigmapharm's payment requests of certain additional research and development and equipment expenses ordered by Rising-Aceto for commercialized drug products; and (c) address and eliminate all of those negative accrual problems discussed in the meeting.

63. At the May 23, 2017 meeting, Rising and Aceto also stated that they were looking to hire a reputable accounting firm, Eisner-Amper, to audit, revise, reorganize and restate their accounting books with regard to Rising-Aceto's fiscal year of 2017, which includes the last two calendar quarters of 2016 and the first two calendar quarters of 2017.

64. Indeed, on June 2, 2017, Rising-Aceto's Vice President, Mr. Hazaray, informed Sigmapharm's Vice President, Mr. Kremer, that the Eisner-Amper firm had been hired by



Rising-Aceto to also study the data that led to Sigmapharm's December 16, 2016 notice of breach, and to audit Rising-Aceto's accounting recording processes of its Sales Expenses and to address the negative accrual accounting inconsistencies discussed in the May 23, 2017 meeting.

65. Thus, during the May 23, 2017 meeting, Rising-Aceto's Vice President, Mr. Hazaray, and Chief Operational Officer, Mr. Kaczmarek, admitted that:

- i. Rising-Aceto's accounting practices followed by the previous Rising-Aceto management were dubious;
- ii. Rising-Aceto's new management hired Eisner-Amper to investigate and correct its accounting practices for the Sigmapharm Products;
- iii. Rising and Aceto were both committed to expeditiously resolve Sigmapharm's claims soon after Eisner-Amper issued their report; and
- iv. Rising-Aceto would provide a copy of the Eisner-Amper report to Sigmapharm.

66. On June 12, 2017, Rising-Aceto confirmed that Eisner-Amper had begun their investigation and in 2-3 weeks would be able to share the accountants' findings with Sigmapharm.

67. As of today, however, and despite repeated requests by Sigmapharm, Rising-Aceto have refused to: (a) provide a copy of the Eisner-Amper report; (b) respond with complete data and transparent information to the accounting discrepancies, underpayments and audit from 2016; (c) provide all necessary data to reconcile the Profit Sharing payments Rising-Aceto made to Sigmapharm to date; (d) provide any marketing plan and supply forecast covering 2018 for Sigmapharm's review and consideration; and (e) discontinue the improper accounting practices for the calculation of Sigmapharm's Profit Sharing.

68. Thus, for ten (10) months after the May 23, 2017 meeting at Sigmapharm's offices in Bensalem, Pennsylvania, Rising-Aceto failed to cure the material breaches of the Agreement of which Sigmapharm placed them on notice on December 16, 2016.

**Rising-Aceto's Attempts To Divert Attention  
From Their Fraudulent Accounting Practices**

69. Sigmapharm has always approached its relationship with Rising and Aceto in good faith and, therefore, the true implications of the statements and admissions made by Rising-Aceto's representatives in the May 23, 2017 meeting discussed above, did not become apparent to Sigmapharm until recently and after the events described below.

70. On June 9, 2017, Sigmapharm requested Rising-Aceto to provide: (a) the status of each item in Sigmapharm's December 16, 2016 notice of breach; (b) information to support a renewed request for a Sigmapharm audit for Q2-16 through Q1-17; and (c) whether Rising-Aceto had yet established with certainty the concrete reason for the negative accrued Sales Expenses reported in those 4 calendar quarters.

71. Subsequently, on June 12, 2017, Rising-Aceto's Vice President, Mr. Hazaray, simply responded via email that the Eisner-Amper firm had started their audit on June 8, 2017, and had estimated 2 to 3 weeks to complete it. No response was provided about the other matters inquired by Sigmapharm on June 9, 2017.

72. On June 27, 2017, Mr. Hazaray further informed Sigmapharm via email that Rising-Aceto require 7 to 10 more days for Eisner-Amper to complete their study.

73. On July 7, 2017, Rising-Aceto's Vice President, Mr. Hazaray, and their new Chief Financial Officer, Eugene Hughes, and their Financial Supervisor, Scott Elian, told Sigmapharm's Mr. Kremer that Rising-Aceto wanted even more time until the end of July, 2017 to complete their study and respond to all open items.

74. Suddenly, however, instead of transparently addressing Sigmapharm's repeated notices of material breaches of the Agreement, toward the end of July 2017, Rising-Aceto began to contrive disputes with Sigmapharm concerning the calculation of the Cost of Goods ("COGs") in their quarterly accounting reports to Sigmapharm.

75. As a result, Sigmapharm began to realize that Rising-Aceto were using delay tactics and sleight-of-hand distractions to avoid paying Sigmapharm its entire rightful profit share as per the Agreement.

76. Like their prior promises, the August 15, 2017 deadline for Rising-Aceto's payment of Sigmapharm's profit share for Q2-17 (ending on June 30, 2017) had come and gone, and still Rising and Aceto had not given to Sigmapharm any accounting information and any payment for that quarter, using as their excuse their perpetual review-audit of their fiscal year-2017, which had also ended one and a half months earlier, on June 30, 2017.

77. On or around August 15, 2017, Sigmapharm reviewed the payments it had received during Rising's-Aceto's fiscal year-2017 (i.e., from Q3-16 through Q2-17), and realized to its dismay that it had only been paid about \$3.56 million for all four quarters of the fiscal year-2017 so far. However, based on publicly available commercial sales data of Sigmapharm's Flucytosine Capsules unique, sole-sourced generic product sold exclusively by Rising-Aceto in the United States market during that period, Sigmapharm should have received approximately \$17.5 million for those four quarters of fiscal year-2017.

78. Additionally, in the meantime, the precipitous drop of Rising-Aceto money deposited, as the quarterly profit share of Sigmapharm, to its bank accounts had been detected by TD Bank, which informed Sigmapharm on August 23, 2017, that it would be discontinuing Sigmapharm's credit line.

79. Consequently, in mid-August 2017, based on such devastating developments for Sigmapharm and such estimated gross underpayment for the fiscal year-2017 of approximately \$14 million (since about \$3.56 million had been received for Q3-16 and Q4-16), Sigmapharm re-notified Rising-Aceto of their ongoing serious breaches of the Agreement.

80. In response, and while still claiming that their review of Sigmapharm's profit share for their whole fiscal year-2017 was not yet complete due in part to their newly contrived issues related to the COGs calculation, Rising and Aceto made a purported "good faith" installment of \$2.5 million to Sigmapharm on August 28, 2017.

81. There was nothing "good faith" about this \$2.5 million belated and partial payment.

82. This certainly did not cure Rising-Aceto's material breaches of the Agreement.

**Rising-Aceto Concede The Existence Of Multi-Million Underpayments That Irreparably Harms Sigmapharm But They Continue To Hide The Extent Of Their Fraud**

83. On September 15, 2017, after almost four months from the May 23, 2017 meeting at Sigmapharm's facilities, during which Rising-Aceto promised Sigmapharm that they would "immediately" look into and resolve all open issues, Rising-Aceto finally sent Sigmapharm their new, revised profit share accounting for the whole fiscal year-2017.

84. Rising-Aceto failed to provide the detailed back-up for such revised accounting.

85. The accompanying detailed supporting information was still missing sufficient data fields to allow Sigmapharm to determine the correctness and accuracy of Rising's newly presented profit share accounting file. Based on the reported partial data, in their initial draft form, Sigmapharm realized that it should have been paid a total profit share sum of at least \$11,230,771 for the whole fiscal year-2017

86. Moreover, in the same file, Rising-Aceto included a full-year "Adjusted Profit

Share” value indicating that Sigmapharm should have been actually paid an additional \$1,120,951 above the figure calculated in Rising-Aceto’s draft reporting contained in the same file, reaching a new, adjusted total profit share sum of \$12,351,722 for the four quarters of fiscal year-2017.

87. In fact, about one week later, on September 22, 2017, Rising-Aceto provided two additional files titled: “Sigma Pharm FY 2017 Recast by Qtr (9-20-17).xlsx” and “Rising Cash Basis Review (9-21-17).xlsx.” In both of these files, Rising-Aceto further revised and restated their initially adjusted profit share accounting for their fiscal year-2017 concluding “miraculously” that Sigmapharm should have been actually paid an additional \$278,208 as compared to their reporting of just the previous week, reaching now a new total profit share sum for Sigmapharm of \$12,629,930 for the whole fiscal year-2017.

88. Because Sigmapharm had only been paid by that time \$3,564,490 for the whole fiscal year-2017 as Q3-16 and Q4-16 profit share payments, it became apparent that, by mid-August 2017, Sigmapharm was indeed grossly underpaid by at least \$9,065,440 for its profit share earned in fiscal year-2017 based on Rising-Aceto’s own accounting figures, which, even to this day, cannot be actually validated by Sigmapharm since Rising-Aceto has not yet provided to Sigmapharm its requested (since June 9, 2017) relevant auditable information to verify and/or recalculate such accounting figures on a cash basis as the Agreement requires.

89. Sigmapharm, without waving its rights under the terms of the Agreement, received partial payments under Rising-Aceto’s accrual accounting methodology based on their promise to soon provide the appropriate and complete relevant cash based accounting data and information in order for Sigmapharm to audit and determine its correct profit share on a cash basis accounting as actually required by the Agreement.

90. Due to its dangerously severe lack of cash flow at that time, Sigmapharm agreed to accept Rising-Aceto's offer to make a second purported "good faith" partial installment to Sigmapharm of only \$3.5 million, which was made on September 25, 2017.

91. Combined with Rising-Aceto's first purported "good faith" installment of \$2.5 million made on August 28, 2017, the new installment raised the total sum of Rising-Aceto's "good faith" installments to \$6 million.

92. Therefore, by the end of September 2017, three months after the end of fiscal year-2017, Sigmapharm remained severely underpaid, as per Rising-Aceto's own accounting figures, by almost \$3.1 million for that fiscal year.

93. After continuous demands from Sigmapharm's CEO, Dr. Spireas, to Rising-Aceto's COO, Mr. Kaczmarek, Rising-Aceto made an additional third purported "good faith" installment of another \$1.5 million on October 13, 2017, leaving a still unpaid amount of profit share due to Sigmapharm of \$1,565,440 for the four calendar quarters Q3-16, Q4-16, Q1-17 and Q2-17.

94. This unpaid profit share amount was finally paid to Sigmapharm on November 1, 2017, as part of a greater payment that included Rising-Aceto's cash based profit share payment of \$1,392,292 due to Sigmapharm for Q3-17.

95. However, the promised complete cash based accounting information for Q2-16 through Q2-17 requested by Sigmapharm since June 9, 2017, has not yet been provided to this day, more than nine (9) months later.

96. Sigmapharm is not a bank. It is a developer, marketer, licensor, manufacturer and a business with commercially innovative pharmaceutical technologies and products located in Pennsylvania, which employs more than one hundred Pennsylvania residents.

97. Rising-Aceto's bad faith and trickled accounting and payment practices have irreparably harmed Sigmapharm and the business relations between Sigmapharm and Rising-Aceto, especially in light of the fact that all revised and restated accrued profit share accounting reports of Rising-Aceto for the calendar quarters Q2-16 through Q4-17 still continued to contain negative accruals for the Sales Expenses despite Rising-Aceto's promises to the contrary.

**Rising-Aceto Are Up To The Same Old Tricks And Have Not Only Breached The Agreement And Assignment, But Have Been Unjustly Enriched While Defrauding Sigmapharm And To The Detriment Of The Public**

98. As discussed above, on November 1, 2017, Rising-Aceto reported to and paid Sigmapharm a profit share total of \$1,392,292 for Q3-17.

99. On November 15, 2017, Rising-Aceto reluctantly agreed to pay yet another purported "good faith" installment of \$500,000 for feared accounting discrepancies in that quarter as well, since Rising-Aceto had again alarmingly reported negative accruals for the Sales Expenses of Q3-17, despite their promises to the contrary.

100. After complete silence regarding the entire Q4-17, Rising and Aceto finally provided information for the last calendar quarter of 2017 on February 16, 2018. They did so only after being reminded by Sigmapharm that the information and payment for Q4-17 were both due on or before February 14, 2018.

101. Along with this information was a recalculation of the profit share accounting figures for Q3-17. Not only had Rising and Aceto again underpaid Sigmapharm for Q3-17 by their initial payment of \$1,392,292 on November 1, 2017 and their additional \$500,000 amount reluctantly paid as a purported "good faith" installment on November 15, 2017, but also, as per Rising-Aceto's own newly "adjusted" accounting figures, an additional \$319,471 was actually owed to Sigmapharm for that quarter.

102. Even though this amount was paid on February 16, 2018, this situation, along with the persistent reporting of negative accruals for their whole fiscal year-2017 and for Q3-17 and Q4-17 discussed above, clearly demonstrate that Rising and Aceto are not acting in good faith since they are persistently continuing their erroneous reporting practices of negative accrued Sales Expenses, while overstating the actual, cash based, Sales Expenses.

103. Sigmapharm has been continuously cheated by Rising-Aceto and significantly underpaid with regard to its rightful profit share to which Sigmapharm is entitled to in each and every calendar quarter.

104. During the last six calendar quarters alone (i.e., from Q3-16 through Q4-17), Rising-Aceto significantly inflated their cash basis accounting calculations for the actual Sales Expenses in order to make significantly reduced cash basis payments to Sigmapharm as compared to the correct profit share payments that should have been calculated and made by Rising-Aceto according to the Agreement.

105. The ongoing refusal of Rising-Aceto to provide the complete accounting and support of their actual Sales Expenses for each of those six quarters in order to be correctly calculated and accounted on a cash basis as per the Agreement, demonstrates the extent and nature of Rising's and Aceto's fraud perpetrated on Sigmapharm.

106. Sigmapharm was and is suffering ongoing and irreparable harm at the hands of Rising and Aceto and their defrauding tactics, while constantly watching its cash flow seriously diminishing by the month in a manner totally against its budgetary projections.

107. As a result, not only for Sigmapharm but also for the public, several of Sigmapharm's unique pharmaceutical projects under research and development that would have provided inexpensive unique, sole-sourced, generic drug products to the health care community,



have been delayed to the point that some have been already discontinued and others are in danger to follow suit today.

108. On the other hand, Rising and Aceto have benefitted significantly. By defrauding Sigmapharm and, on further information and belief, other vendors and collaborators similar to Sigmapharm, Aceto was able to show the investing public significantly higher cash balances and, potentially, more profits than those actually obtained by using the plasmatic negative accruals of its Sales Expenses to significantly underpay Sigmapharm and falsely demonstrate for each quarter more cash availability and, potentially, more earnings than actual.

109. Therefore, based on the aforementioned facts, and on information and belief, Sigmapharm believes and therefore avers that Rising and Aceto clearly intended to defraud and harm Sigmapharm in order to obtain the benefits discussed above, while at the same time knowing that such fraud would have resulted in the incalculable and irreparable harm to Sigmapharm and the public.

110. Rising and Aceto are very familiar with Sigmapharm's proven ability and talent in the pharmaceutical field to develop unique, sole-sourced, generic drug products.

111. In fact, during the May 23, 2017 meeting, and in subsequent meetings at Sigmapharm's offices in Bensalem, Pennsylvania, Rising and Aceto came prepared and willing to negotiate a possible acquisition of, or new collaboration for, some of Sigmapharm's unique generic drug products in existence or under research and development.

112. Indeed, Rising-Aceto themselves have sold several of such Sigmapharm unique products through the Agreement, such as the generic Disulfiram Tablets, Griseofulvin Tablets and Flucytosine Capsules.

113. Rising and Aceto and, indeed, the pharmaceutical industry, are well aware of

other unique generic products of Sigmapharm, which it currently manufactures and markets by itself, such as Adefovir Dipivoxil Tablets, Liothyronine Sodium Tablets, Sodium Phenylbutyrate Powder, and other unique new generic products already known publicly to have been submitted to the FDA by Sigmapharm with first-to-file Paragraph-IV certifications (which imply at least a six-month marketing exclusivity), such as the unique generic Asenapine Maleate Tablets, Ticagrelor Tablets, Rivaroxaban Tablets and Apixaban Tablets.

114. Furthermore, and rather disturbingly, Rising-Aceto unilaterally decided to significantly decrease the pricing of several Sigmapharm Products they are marketing and distributing exclusively without informing, and confirming with, Sigmapharm about such unilateral drastic price decreases in gross violation of the Agreement and in bad faith.

115. Based on the devious and fraudulent actions of Rising-Aceto discussed herein, and on information and belief, Sigmapharm believes and therefore avers that the prices of certain of the Sigmapharm Products facing generic competition have been substantially reduced by Rising-Aceto, over a relatively short period of time, to levels lower, and in some instances significantly lower, than the prices at which similar, competitive generic products are sold by competitors.

116. And yet, Rising-Aceto are commanding much less share of the generic market in which Sigmapharm Products compete.

117. This is either gross incompetence or fraud by Rising-Aceto, and certainly does not represent the Commercially Reasonable Efforts required by the Agreement.

118. Rising-Aceto never discussed these inconsistencies with Sigmapharm to create new marketing plans and strategies to address these issues.

119. Rising-Aceto never proposed to Sigmapharm the possible discontinuance of the

marketing and sale of certain Sigmapharm Products which, in some instances, such as in the cases of Amiloride Hydrochloride Tablets and Protryptiline Hydrochloride Tablets, are actually losing money, or are on the threshold of showing losses, for both Sigmapharm and Rising for approximately seven or eight consecutive calendar quarters.

120. Based on the facts discussed above, and on information and belief, Sigmapharm believes and therefore avers that Rising and Aceto used underhanded and fraudulent tactics to market and sell such generic Sigmapharm Products with the intent to defraud and deprive Sigmapharm of its entire rightful profit share for such products.

121. Specifically, Sigmapharm believes and therefore asserts that Rising and Aceto “bundled” the sale of one or more of such Sigmapharm Products at a relative severe loss, thereby making such Sigmapharm products the “loss-leaders” of the “bundle” offered for sale in order to entice customers to purchase the whole “bundle” containing other Rising-Aceto owned or controlled products that are not related to the generic Sigmapharm Products.

122. Accordingly, Sigmapharm now believes that its previously, until lately unique, generic Sigmapharm Product of Flucytosine Capsules, which has recently obtained generic competition, will be soon annihilated in a manner similar to that described in the preceding paragraphs due to Rising-Aceto’s incompetence or fraudulent tactics against Sigmapharm.

123. Because of the long-term pattern of breaches by Rising and Aceto, their refusal to provide the contractually mandated back-up accounting information, and other bad faith conduct set forth above, it is clear that if this “collaboration” continues, Sigmapharm will continue to suffer ongoing irreparable harm at the hands of the Defendants Rising and Aceto.

124. As more fully set forth above, Defendants’ forgoing activity constitutes a material breach of the Agreement, for which they failed to cure.

125. Defendants' failure to cure is a material breach of their contractual obligations to Sigmapharm, which entitled Sigmapharm to terminate the Agreement.

126. Accordingly, the Agreement has been terminated since no resolution offered, or action taken, by Rising-Aceto has or can fully cure the deficiencies, fraud, harm and damages perpetrated against Sigmapharm.

127. Because of Sigmapharm's termination, and because of Rising-Aceto's breaches and misconduct set forth herein, this Court must declare that Sigmapharm is the sole owner of the Sigmapharm Products including their relevant ANDAs and has all of the exclusive marketing and distribution rights of all Sigmapharm Products and any other drugs covered by the Agreement free of any obligations to Rising-Aceto, and Defendants shall immediately transfer any rights they claim in the Sigmapharm Products to Sigmapharm for one (\$1) dollar.

128. Additionally, as also more fully set forth above, Defendants' forgoing activity constitutes fraud and/or other tortious misconduct against Sigmapharm in the claims set forth below.

## **COUNT I**

### **DECLARATORY AND INJUNCTIVE RELIEF**

129. Plaintiff incorporates by reference the allegations contained in the foregoing paragraphs as if fully set forth herein.

130. This is a claim for declaratory judgment pursuant to 28 U.S.C. §2201 for the purpose of determining a question of actual controversy which exists and is imminent and inevitable between the parties as set forth above.

131. 28 U.S.C. §2201 is liberally construed to accomplish its intended purpose of affording a speedy and inexpensive method of adjudicating legal disputes and settling legal

rights and remove uncertainty and insecurity from legal relationships without awaiting a violation of rights.

132. Plaintiff seeks a declaration that Defendants Rising and/or Aceto are in material breach of the Agreement for their performance, financial, reporting and marketing obligations, and an order requiring them to provide complete and up-to-date source information regarding their reporting of their Net Sales and of Sigmapharm's share of the Net Profits on a cash basis as provided for in the Agreement.

133. Plaintiff seeks injunctive and equitable relief ordering Rising-Aceto to be audited by Sigmapharm's accountants, and/or by independent outside forensic accountants with expertise in pharmaceutical and drug marketing, distribution, sales and profits.

134. Sigmapharm also seeks a declaration that Defendants Rising and/or Aceto are in material breach of their marketing and distribution obligations and an order directing that the rights, including to all marketing and distribution, of all of the drugs and Sigmapharm Products covered by the Agreement be immediately returned to Sigmapharm.

135. Plaintiff Sigmapharm also seeks a declaration that the Agreement has been terminated for Defendants' failure to cure material breaches as more fully described above.

136. Plaintiff Sigmapharm also seeks a declaration that Sigmapharm is the sole owner of the Sigmapharm Products including their relevant ANDAs and has all of the exclusive marketing and distribution rights of all Sigmapharm Products and any other drugs covered by the Agreement free of any obligations to Rising-Aceto, and an order requiring that Defendants shall immediately transfer any rights they claim in the Sigmapharm Products to Sigmapharm for one (\$1) dollar.

WHEREFORE, Plaintiff Sigmapharm respectfully requests judgment in its favor and

injunctive and equitable relief against Defendants Aceto and Rising, including:

- 1) Declaring Rising and Aceto to be in material breach of their performance, financial, reporting and marketing obligations to Sigmapharm under the Agreement and Assignment;
- 2) Ordering Rising and Aceto to provide to Sigmapharm within ten (10) days all of the back-up data and information for the Quarterly Accounting for the period starting from the Second Calendar Quarter of 2009 through the present, including the Eisner-Amper report relating to Sigmapharm Products and all of electronic and hard copy data for the accounting of all quarterly reports;
- 3) Ordering Rising and Aceto to be audited by Sigmapharm's accountants and/or with independent outside forensic accountants with expertise in pharmaceutical and drug marketing, distribution, sales and profits;
- 4) Ordering Rising and Aceto, within ten (10) days to transition to Sigmapharm all of the marketing and exclusive distribution rights of the Sigmapharm Products and any other drugs covered by the Agreement;
- 5) Declaring that Rising and Aceto are not co-owners of the Sigmapharm Products and any other drugs covered by the Agreement;
- 6) Declaring that Sigmapharm receives all of the benefits in the Agreement concerning termination, including that it is the sole owner of the Sigmapharm Products and their corresponding regulatory filings and approved ANDAs, and is free of any obligations to Rising and/or Aceto;
- 7) Ordering Defendants to immediately transfer any rights they claim in the Sigmapharm Products and any other drugs covered by the Agreement to Sigmapharm for one

(\$1) dollar; and

8) Award such other and further relief to Sigmapharm as the Court deems just and proper.

## **COUNT II**

### **BREACH OF CONTRACT**

137. All the foregoing paragraphs are incorporated herein by reference as if fully set forth.

138. As more fully set forth above, Defendants entered into the Agreement and Assignment with Sigmapharm. *See* Exhibits “A” and “B.”

139. Defendants breached their Agreement and Assignment with Sigmapharm by, *inter alia*, failing to provide complete and up-to-date source information regarding their reporting of their Net Sales and of Sigmapharm’s share of the Net Profits on a cash basis as provided for in the Agreement.

140. Defendants breached their Agreement with Sigmapharm by, *inter alia*, failing to pay, and/or timely pay, Sigmapharm all payments due under the Agreement, including its share of the Net Profits on a cash basis as provided for in the Agreement.

141. Without Defendants’ promise to provide complete and up-to-date source information regarding their reporting of their Net Sales and to pay all of Sigmapharm’s share of the Net Profits on a cash basis as provided for in the Agreement, Sigmapharm would not have entered into the Agreement and the Assignment.

142. Defendants have the means, ability and financial wherewithal to perform their obligations under the Agreement and Assignment, and/or to pay Sigmapharm its compensatory damages to complete Defendants’ contractual obligations.

143. As a direct result of Defendants' breach of contract, Sigmapharm has suffered damages in excess of the jurisdictional amount, for which Defendants are jointly and severally liable, including damages set forth herein, consequential and incidental damages, and lost profits.

144. Additionally, Defendants are obligated to pay statutory interest on the amounts owed to Sigmapharm under the Agreement and Assignment, including pre-judgment and post-judgment interest.

WHEREFORE, Plaintiff Sigmapharm respectfully demands judgment against Defendants for compensatory damages in excess of the jurisdictional amount, an accounting, together with costs of this action, pre and post-judgment interest, such other damages for delay as are provided by law, and such other and further relief in its favor as the Court deems proper.

### **COUNT III**

#### **PROMISSORY ESTOPPEL/DETRIMENTAL RELIANCE**

145. All the foregoing paragraphs are incorporated herein by reference as if fully set forth.

146. Alternatively, and in the absence of finding breach of contract, Sigmapharm justifiably relied on Defendants' promises and assurances to pay Sigmapharm's full and correct share of the Net Profits on a cash basis, to enter into the Assignment, and in continuing to operate under the Agreement.

147. Defendants failed to fulfill their promises and assurances.

148. Sigmapharm has suffered loss of all it expended by its reasonable and justified reliance on Defendants' promises and assurances, as more fully set forth above.

149. As a direct result of Defendants' misconduct, Sigmapharm has suffered damages in excess of the jurisdictional amount, for which Defendants are jointly and severally liable,



including damages set forth herein, consequential and incidental damages, and lost profits.

150. Based on the foregoing and the averments herein, Sigmapharm is alternatively entitled to an award of such sums appropriate to render it whole, under principles of promissory estoppel and detrimental reliance, in all amounts expended in reliance upon Defendants' aforesaid promises and assurances.

WHEREFORE, Plaintiff Sigmapharm respectfully demands judgment against Defendants for compensatory damages in excess of the jurisdictional amount, an accounting, together with costs of this action, pre and post-judgment interest and such other damages for delay as are provided by law, and such other and further relief in its favor as the Court deems proper.

#### **COUNT IV**

##### **UNJUST ENRICHMENT/QUANTUM MERUIT**

151. All the foregoing paragraphs are incorporated herein by reference as if fully set forth.

152. Alternatively, and in the absence of damages for breach of contract and/or promissory estoppel, Defendants were, are and will be unjustly enriched by Sigmapharm, and Sigmapharm suffered, suffers and will suffer loss of all it expended by its reasonable and justified reliance on the promises and assurances of Defendants, as more fully set forth above.

153. As set forth above, Sigmapharm relied in good faith upon Defendants' promises, and would not have entered into the Agreement and Assignment if it had known that Defendants would not pay Sigmapharm's full share of the Net Profits on a cash basis and all other payments due as provided for in the Agreement.

154. As more fully set forth above, and as a result of Defendants' inducement to Sigmapharm to enter into the Agreement and Assignment, Defendants have been unjustly

enriched in an amount in excess of the jurisdictional amount.

155. Additionally, as more fully set forth above, and as a result of Defendants' inducement to Sigmapharm to enter into the Agreement and Assignment, Defendants have been unjustly enriched in an amount in excess of the jurisdictional amount by keeping exclusive rights to market, sell and distribute Sigmapharm Products.

156. Sigmapharm reasonably relied upon Defendants' misrepresentations and material omissions, and on their actions in continuing to operate under the Agreement.

157. As a direct result of Defendants' misconduct, Sigmapharm has suffered damages in excess of the jurisdictional amount, for which Defendants are jointly and severally liable, including damages set forth herein, consequential and incidental damages, and lost profits.

158. Accordingly, and alternatively to the relief and claims requested above, it would be inequitable and unjust to allow Defendants to keep the benefits derived from Sigmapharm without compensating Sigmapharm, and/or without returning sole ownership and exclusive rights of the Sigmapharm Products to Sigmapharm.

WHEREFORE, Plaintiff Sigmapharm respectfully demands judgment against Defendants for compensatory damages in excess of the jurisdictional amount, an accounting, together with costs of this action, pre and post-judgment interest and such other damages for delay as are provided by law, the return of its sole ownership of Sigmapharm Products and exclusive rights to market, sell and distribute Sigmapharm Products and such other and further relief in its favor as the Court deems proper.

## **COUNT V**

### **FRAUD**

159. All the foregoing paragraphs are incorporated herein by reference as if fully set

forth.

160. As more particularly set forth above, Defendants intentionally and without justification perpetrated a fraud upon Plaintiff.

161. Rising and Aceto were obligated to readily manage and maintain in a simple, transparent and auditable manner using only cash based accounting, all the supporting information and documentation related to the actual Sales Expenses made in each certain calendar quarter in order to calculate on a cash basis the appropriate quarterly profit share due to Sigmapharm.

162. Rising and Aceto agreed that no Sales Expenses related to Sigmapharm Products will be accrued in this accounting process.

163. Instead, unbeknownst to Sigmapharm, Rising and Aceto decided to fraudulently conceal within the quarterly actual, cash based Sales Expenses accrued Sales Expenses.

164. Rising and Aceto have concealed and misrepresented the correct, actual, cash based and transparent accounting information to further conceal their fraudulent activities and prolong their unjust enrichment and gross public misrepresentations of their quarterly financial statements to the detriment of Sigmapharm and the investing public and the consumer public.

165. Defendants' acts in carrying out their fraudulent scheme, conspiracy and artifice to defraud Plaintiff create joint and several liability, without limitation, for the damages incurred by Plaintiff as a result of the fraudulent misrepresentations, omissions and actions of Defendants.

166. As more fully set forth above, Defendants made false, misleading and material misrepresentations and omissions to Plaintiff with the knowledge of their falsity and/or with reckless disregard for their truth.

167. Defendants' acts in furtherance of their fraud and misconduct are further set forth

in this Complaint.

168. As set forth above, each Defendant knowingly and substantially aided, abetted and benefited from said tortious misconduct.

169. Had Plaintiff known of such misconduct, it would not have allowed Rising and Aceto to continue to market, distribute and sell Sigmapharm Products, and for them to calculate, account and distribute Sigmapharm's profits.

170. Additionally, at the time Rising-Aceto made their representations and warranties for the Assignment request to Sigmapharm, Rising and Aceto knew, and had reason to know, that said representations and warranties were materially false because, *inter alia*, they kept delivering to Sigmapharm profit sharing payments and false information that in fact constituted an elaborate subterfuge to impede, impair, foreclose, preclude, and/or otherwise defraud and commercially frustrate Sigmapharm's contractual rights under the Agreement and to use Sigmapharm Products for their own marketing purposes and monetary benefits, thus, injuring Sigmapharm's business and commercial reputation.

171. These material omissions were not apparent or ascertainable in any of the correspondence exchanged between Rising-Aceto and Sigmapharm prior to the consummation of the Assignment and acceptance of each Profit Sharing payment and subsequent accounting.

172. The acts committed by Defendants as set forth above constitute fraud.

173. Defendants were all aware of the material misrepresentations and omissions made by each other to Plaintiff, and they conspired with each other to fraudulently steal, convert and divert Plaintiff's property, assets and funds.

174. Plaintiff reasonably relied upon Defendants' misrepresentations and material omissions.


175. As a direct and proximate result of Defendants' misconduct, omissions and misrepresentations, Plaintiff has been irreparably harmed and has incurred substantial damages in excess of the jurisdictional amount, including but not limited to the damages described above, for which Defendants are jointly and severally liable.

176. The above described misconduct and misrepresentations are outrageous, willful, intentional, false, malicious, reckless, wanton and in bad faith, and done with the willful disregard for the interests of Plaintiff, for which an award of punitive damages is warranted.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory damages in excess of the jurisdictional amount, and the return of its exclusive rights to market and distribute Sigmapharm Products, together with costs of this action, pre and post-judgment interest and such other damages for delay as are provided by law, punitive damages, equitable and injunctive relief, an accounting, and such other and further relief in Plaintiff's favor as the Court deems proper.

**JURY DEMAND**

Plaintiff, Sigmapharm Laboratories, LLC hereby demands a trial by jury.

  
HENRY F. SIEDZIKOWSKI (PA30458)  
TIMOTHY T. MYERS (PA46959)  
ELLIOTT GREENLEAF, P.C.  
925 Harvest Drive, Suite 300  
Blue Bell, PA 19422  
(215) 977-1000

Dated: March 23, 2018

# EXHIBIT “1”

**MASTER PRODUCT DEVELOPMENT AND COLLABORATION  
AGREEMENT**

THIS AGREEMENT (the "**Agreement**") is entered into as of June 22, 2006, by and between **Rising Pharmaceuticals, Inc.**, a corporation organized and existing under the laws of the state of New Jersey including its subsidiaries and Affiliates (as defined below) (collectively hereinafter referred to as "**Rising**") and having a place of business at 3 Pearl Court, Suite A & B, Allendale NJ 07401 and **SigmaPharm Laboratories, LLC** a corporation organized and existing under the laws of the state of Pennsylvania, including its subsidiaries and Affiliates (as defined below) (collectively hereinafter referred to as "**SigmaPharm**"), and having a place of business at 860 Town Center Drive, Langhorne, PA 19047. Rising and SigmaPharm may each be referred to herein individually as a "**Party**" and collectively as the "**Parties**."

\* and at :  
3345 Progress Dr.  
Bensalem, PA 19004

**WHEREAS**, SigmaPharm has certain expertise and technology relating to the development and manufacture of solid dose form pharmaceutical products and obtaining regulatory approval for such pharmaceutical products and Rising has certain expertise relating to the marketing, distribution and sale of pharmaceutical products;

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**WHEREAS**, the Parties desire, from time to time, to collaborate with each other in a cost and profit sharing arrangement related to the shared ownership or licensing of regulatory approvals for certain generic and/or pharmaceutical drugs having the generic equivalents to the Reference Product(s) and to invest their respective resources in developing, obtaining regulatory approval for, manufacturing and marketing such drugs, each as set forth on a schedule executed and attached hereto (each, a "**Schedule**"); and

**WHEREAS**, each Schedule shall delineate the specific terms and conditions related to each new Product collaboration including, but not limited to, a description of the Product to be developed, the percentage allocation of costs and profits, and whether the Parties shall share ownership in the related regulatory approvals for such Product or the rights to such regulatory approvals shall be licensed by SigmaPharm to Rising.

**NOW THEREFORE**, in consideration of the foregoing premises, the mutual promises and covenants contained herein, and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties hereby agree as follows:

**1. DEFINITIONS.**

The following capitalized terms shall have the following meanings for all purposes of this Agreement:

- 1.1. "**Act**" shall mean the Food, Drug and Cosmetics Act, as amended.
- 1.2. "**Active Ingredient**" shall mean the active ingredient specified in **Schedule 1.2**, which is the active ingredient in the Products.

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1.3. **"Additional Bioequivalence Studies"** shall have the meaning set forth in **Section 3.1** of this Agreement.

1.4. **"Affiliate"** of any Party shall mean any corporation, partnership, association, trust, or other business entity or organization, directly or indirectly Controlling, Controlled by, or under common Control with such Party.

1.5. **"Allocated Overhead"** shall mean that portion of SigmaPharm's or its Affiliates' office and administrative expenses, including, but not limited to, rent, utilities and other facility expenses, facility and equipment maintenance, labor (other than Direct Labor), insurance (other than as specified below in **Section 13.6**) and any needed contract manufacturing and testing allocated to the manufacture, testing, release, packaging and ongoing regulatory reporting of the Products for sale or distribution in the Territory calculated in accordance with generally accepted accounting principles not to exceed the amount set forth in **Schedule 1.5**. Unless the increase is pre-approved by Rising, the Allocated Overhead shall not increase from one (1) year to the next by more than an amount equal to the lesser of the annual percentage increase in the Producers' Price Index for the preceding year or five percent (5%).

1.6. **"ANDA"** or **"NDA"** shall mean a duly prepared abbreviated new drug application, new drug application or similar health registration application that is or will be filed with national or supra-national health registration authorities for the purpose of obtaining Regulatory Approval to market the Product in one or more states of the Territory.

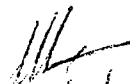
1.7. **"Calendar Quarter"** shall mean the respective periods of three consecutive calendar months ending on March 31, June 30, September 30 or December 31, for so long as this Agreement is in effect.

1.8. **"Commercially Reasonable Efforts"** shall mean efforts and resources normally used by a Party for a product owned by it or to which it has rights, which is of similar market potential at a similar stage in its development or product life, taking into account issues of safety and efficacy, product profile, the competitiveness of the marketplace, the proprietary position of the compound or product, the regulatory structure involved, raw material availability, difficulty of formulation and manufacture, the profitability of the applicable products, and other relevant factors.

1.9. **"Confidential Information"** shall have the meaning set forth in **Section 10.1** of this Agreement.

1.10. **"Continuing Party"** shall have the meaning set forth in **Section 12.5.3** of this Agreement.

1.11. **"Control"** shall mean: (i) in the case of corporate entities, direct or indirect ownership of more than fifty percent (50%) of the stock or shares having the right to vote for the election of directors; and (ii) in the case of non-corporate entities, direct or

  
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indirect ownership of at least fifty percent (50%) of the equity interest with the power to direct the management and policies of such non-corporate entity.

1.12. **"Co-Owned Products"** shall mean those products as described in **Section 4.2.1** of this Agreement and set forth in **Schedule 4.2.1**.

1.13. **"Cost of Goods"** shall mean the amount contingently charged by SigmaPharm to Rising for the purchase of Products to be sold or distributed pursuant to this Agreement, which amount shall not exceed SigmaPharm's Transfer Price incurred in manufacturing such Products for Rising hereunder.

1.14. **"Development Costs"** shall mean those costs incurred by the Parties or their respective Affiliates in connection with developing the Products, including but not limited to, formulation development, bio-batch manufacturing, Initial Bioequivalence Studies and ANDA filings.

1.15. **"Development Cost Percentage"** shall mean the percentage of Development Costs allocated to each Party related to the development of Co-Owned Products.

1.16. **"Direct Labor"** shall mean the wages, taxes and benefits incurred by SigmaPharm or its Affiliates in connection with manufacturing Products for sale or distribution in the Territory hereunder directly involved in the manufacture of the Product(s).

1.17. **"Disclosing Party"** shall have the meaning set forth in **Section 10.1** of this Agreement.

1.18. **"Distribution Cost(s)"** shall mean the amount paid by Rising directly related to the distribution of the Products, including but not limited to, insurance, storage costs and Freight or transportation costs not reimbursed by the customer.

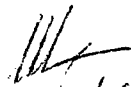
1.19. **"Effective Date"** shall mean the date of execution of the first Schedule to this Agreement by both Parties.

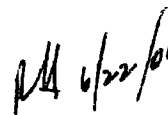
1.20. **"FDA"** shall mean the United States Food and Drug Administration Agreement.

1.21. **"Freight"** shall mean transportation and insurance costs relating directly to transportation of the Product(s). Rising shall arrange and pay for the Freight from SigmaPharm to Rising and from Rising to the purchasers of the Product.

1.22. **"FTC"** shall mean the United States Federal Trade Commission.

1.23. **"Good Clinical Practice"** or **"GCP"** shall mean the then current standards for clinical trials for pharmaceuticals as set forth in the Act and applicable regulations promulgated thereunder, as amended from time to time.

  
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1.24. **"Good Laboratory Practice" or "GLP"** shall mean the then current standards for laboratory activities for pharmaceuticals, as set forth in the Act and applicable regulations promulgated thereunder, as amended from time to time.

1.25. **"Good Manufacturing Practice" or "GMP"** shall mean the then current standards for the manufacture of pharmaceuticals as set forth in the United States Federal Food Drug and Cosmetics Act and applicable regulations promulgated thereunder, as amended from time to time.

1.26. **"Initial Bioequivalence Study"** shall have the meaning set forth in **Section 3.1** of this Agreement.

1.27. **"Initial Marketing Date"** shall be the date listed on the FDA Form 2657 (New Product Listing Form) or its successor, indicating the first date the Product is distributed to customers in the Territory.

1.28. **"Invention(s)"** shall mean an invention conceived and reduced to practice in the course of the performance of and within the scope of this Agreement.

1.29. **"Know-How"** shall mean all proprietary technical and clinical information, data and know-how relating to the Product, whether or not patentable, which is owned or controlled as of the Effective Date or acquired or developed during the term of this Agreement by a Party hereto. Know-How shall include, without limitation, processes, formulas, discoveries and inventions whether relating to biological, chemical, pharmacological, toxicological, pharmaceutical, physical and analytical safety, quality control and clinical data. Know-How shall also include relevant medical information relating to the Product. The term "Know-How" shall not include: (i) any know-how, processes, information and data which is, as of the Effective Date or later, generally available to the public without breach by any Party of its obligations of confidentiality hereunder; or (ii) any general development or manufacturing know-how not specific to the Product.


1.30. **"Liabilities"** shall have the meaning set forth in **Section 13.2** of this Agreement.

1.31. **"License Fee"** shall mean the fee that Rising shall pay to SigmaPharm in exchange for the granting to Rising of an exclusive license for Licensed Products as set forth in **Section 4.4**.

1.32. **"Licensed Product(s)"** shall mean those products as described in **Section 4.2.2** of this Agreement and set forth in **Schedule 4.2.2**.

1.33. **"License Period"** shall mean the initial ten (10) year term of the License, as it applies to Licensed Products. Such License Period shall commence on the "Initial Marketing Date."

  
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1.34. **"Litigation Expenses"** shall mean expenses incurred in defending or litigating any claims or actions related to the Products brought by a Third Party (including reasonable legal fees and the payment of damages and expenses to a Third Party) as set forth in **Section 13.1** of this Agreement.

1.35. **"Marketing Plan"** shall have the meaning set forth in **Section 2.2.3** of this Agreement.

1.36. **"Net Profits"** (or losses as the case may be) shall mean, with respect to any Calendar Quarter, the Net Sales obtained from the sale of Products in the Territory during such Calendar Quarter, less the sum of: (i) Cost of Goods; (ii) Rising's Fee; (iii) amounts repaid or credited by reason of recalls; (iv) pre-approved consulting and legal fees; (v) Litigation Expenses; (vi) the cost of all Product(s) that are unsaleable or no longer marketable; and (vii) any other cost or expense approved by the Parties.

1.37. **"Net Sales"** shall mean, with respect to any Calendar Quarter, the gross amounts ~~invoiced~~ by Rising or its Affiliates for Products sold to any Third Parties during such Calendar Quarter less the sum of: (i) subject to **Section 5.7** below, chargebacks, cash and quantity discounts, returns, invoice adjustments, rebates (e.g. customer and government) and other credits taken by customers or granted by Rising with respect to such Product sales other than as a result of recalls; (ii) invoice adjustments made for errors on invoiced sales included in previous calculations of Net Sales and not yet accounted for; (iii) Freight; and (iv) marketing and advertising expenses (e.g., trade journals, direct marketing, physician detailing, etc.) directly related to the marketing of the Products. Subject to **Section 8.6** below, all deductions listed in the above articles (1.36 and 1.37) shall be transparent and readily available for independent audit purposes.

1.38. **"Non-Continuing Party"** shall have the meaning set forth in **Section 12.5.3** of this Agreement.

1.39. **"Party(ies)"** shall have the meaning set forth in the **Preamble** of this Agreement.

1.40. **"PDMA"** shall mean the Prescription Drug Marketing Act of 1987, as amended.

1.41. **"Percentage"** shall mean the percentage of Net Profits and costs allocated to each Party related to each Product, calculated in accordance with this Agreement and as set forth on **Schedule 1.41**.

1.42. **"Phase(s)"** shall have the meaning set forth in **Section 2.2.1** of this Agreement.

1.43. **"Producers' Price Index"** **"Producers' Price Index"** shall mean the Producers' Price Index published annually by the United States Department of Labor's Bureau of Labor Statistics for the Standard Metropolitan Statistical Area in which SigmaPharm's manufacturing facility is located.

1.44. **“Product(s)”** shall mean a drug product containing the Active Ingredient as an active ingredient in all strengths and presentations, which product is the generic bioequivalent of and therapeutically equivalent to the Reference Product.

1.45. **“Purchase Price”** shall have the meaning set forth in **Section 5.6** of this Agreement.

1.46. **“Raw Materials”** shall mean the active and inactive ingredients, and components, including, but not limited to, labels, bottles, caps, seals, cardboard packaging and inserts, used to manufacture the Product(s).

1.47. **“Receiving Party”** shall have the meaning set forth in **Section 10.1** of this Agreement.

1.48. **“Reference Product”** shall mean the drug product currently marketed and sold under the pharmaceutical brand identified in **Schedule 1.48**.


1.49. **“Regulatory Approval”** shall mean the authorizations and approvals (including, without limitation, approvals of ANDAs, NDAs, supplements and amendments, pre- and post- approvals, pricing and third party reimbursement approvals, and labeling approvals) of any national, supra-national, regional, state or local regulatory agency, department, bureau, commission, council or other governmental entity, necessary for the commercial manufacture, distribution, marketing, promotion, offer for sale, use, import, export and sale of Product(s) in a regulatory jurisdiction within the Territory.

1.50. **“Regulatory Authority”** shall mean any national (e.g., the United States Food and Drug Administration), supra-national, regional, state or local regulatory agency, department, bureau, commission, council or other governmental entity in each and all states of the Territory involved in the granting of Regulatory Approval for the Product.

1.51. **“Remaining Party”** shall have the meaning set forth in **Section 12.3.2** of this Agreement.

1.52. **“Rising’s Fee”** shall be calculated as follows: (i) a distribution fee which shall include Product distribution, shipping, warehousing, rebate and chargeback management, accounting, customer service and inventory financing and shall be equal to the following: in the event that Net Sales are less than \$10 Million, four percent (4%) of such Net Sales; in the event that Net Sales are greater than \$10 Million but less than \$20 Million, three point five percent (3.5 %) of such Net Sales; and in the event that Net Sales are greater than \$20 Million, three percent (3%) of such Net Sales; and (ii) a marketing and sales fee which shall include travel, tradeshow and other sales related expenses, sales administration and sales incentives and shall be equal to the following: in the event that Net Sales are less than \$10 Million, four percent (4%) of such Net Sales; in the event that Net Sales are greater than \$10 Million but less than \$20 Million, three point five percent (3.5%) of such Net Sales; and in the event that Net Sales are greater than \$20 Million, three percent (3%) of such Net Sales.

  
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1.53. **"Rising Projects"** shall refer to those Products that Rising initiates and brings to SigmaPharm and the Parties agree to develop. Each of the Rising Projects shall be Co-Owned Products as set forth in **Section 4.2.1** of the Agreement. Rising's Percentage of Net Profits of such Co-Owned Products shall be forty-five percent (45%) and SigmaPharm's Percentage of Net Profits of such Co-Owned Products shall be fifty-five percent (55%). Rising's Development Cost Percentage of such Rising Projects shall be fifty-five percent (55%) and SigmaPharm's Development Cost Percentage shall be forty-five percent (45%).

1.54. **"Rising Technology"** shall mean all information, data, intellectual property (excluding trademarks and copyrights) and Know-How, whether patentable or not, which is owned or controlled by Rising prior to or during the term of the Agreement and which is necessary or useful in the marketing, distribution and sale of a Product hereunder.

1.55. **"SigmaPharm Projects"** shall refer to those products that SigmaPharm initiates and brings to Rising and the Parties agree to develop. In the event that a SigmaPharm Project is a Co-Owned Product as set forth in **Section 4.2.1** of the Agreement, in connection with the Development Costs, Rising agrees to assume responsibility for an extra ten percent (10%) over Rising's Percentage and SigmaPharm shall be responsible for the balance. For example, if Rising receives a Percentage equal to forty percent (40%) of the Net Profits for a Co-owned Product, Rising shall be responsible for fifty percent (50%) of the Development Costs and SigmaPharm shall be responsible for the remaining fifty percent (50%) of such Development Costs. In the event that a SigmaPharm Project is a Licensed Product as set forth on **Section 4.2.2** of the Agreement, Rising shall not be responsible for the Development Costs and Rising's Percentage of Net Profits of such Licensed Products shall be as set forth on the applicable Schedule.

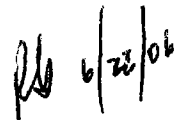
1.56. **"SigmaPharm Technology"** shall mean all information, data, intellectual property and Know-How, whether patentable or not, which is owned or controlled by SigmaPharm prior to or during the term of this Agreement and which is necessary or useful in the development and manufacture of Products, in the development and conduct of bioequivalence studies for the Products, in the preparation and filing for Regulatory Approval for the Products, and in maintaining such Regulatory Approvals.

1.57. **"Specifications"** shall mean the manufacturing specifications in the ANDA.

1.58. **"Territory"** shall mean the United States of America, its territories and possessions (including the Commonwealth of Puerto Rico).

1.59. **"Third Party(ies)"** shall mean any person(s) or entity(ies) other than the Parties and their Affiliates.

  
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1.60. **"Trademark"** means the trade name or trademark used and owned by the Parties in connection with marketing and sale of the Products.

1.61. **"Transfer Price"** shall mean with respect to SigmaPharm's manufacture of Product(s), the fully absorbed manufacturing cost which is equal to the sum of: (i) SigmaPharm's direct Unit costs of Raw Materials, Direct Labor and Allocated Overhead, which costs are calculated in accordance with generally accepted accounting principles and have been incurred by SigmaPharm or its Affiliates in connection with manufacturing Products for sale or distribution in the Territory hereunder; and (ii) an amount equal to fifteen percent (15%) of item (i). **Schedule 1.61** sets forth SigmaPharm's initial estimate of its Transfer Price for each Product. Any change in SigmaPharm's Transfer Price from its estimate disclosed on the applicable schedule shall not be effective unless it provides Rising with not less than thirty (30) days advance written notice thereof, together with documentary evidence of its increased costs for direct Unit costs of Raw Materials, Direct Labor and/or Allocated Overhead if applicable.

1.62. **"Withdrawal Notice"** shall have the meaning set forth in **Section 12.3.2** of this Agreement.

1.63. **"Withdrawing Party"** shall have the meaning set forth in **Section 12.3.2** of this Agreement.

1.64. **"Unit(s)"** shall mean the number and quantity of the Products specified in **Schedule 1.64**.

## 2. **THE COLLABORATION.**

### 2.1. **General Obligations of the Parties.**

2.1.1 The Parties agree to jointly collaborate in the selection of Products and the development, registration and approval, manufacturing and marketing of such Products, as further described in this Agreement and the Schedule(s) attached hereto and incorporated herein (as may be supplemented from time to time). SigmaPharm will be primarily responsible for the development and the manufacture of the Products as further described in **Sections 3 and 5** hereof and for developing and directing of the relevant bioequivalence studies that will be conducted by a Third-Party, preparing and filing applications for Regulatory Approval for the Products in the Territory, maintaining those Regulatory Approvals granted for the Products in the Territory and in obtaining formulary acceptance of the Product at managed care organizations, the latter with the cooperation and collaborative efforts of Rising, as reasonably requested, each as further described in **Section 4** hereof, as applicable. Rising will be primarily responsible for the marketing, distribution and sale of the Products. Rising will also be responsible for customer service, rebate management, billing, warehousing of the finished Products and such other responsibilities as regularly performed by a pharmaceutical distributor.

  
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2.1.2 The Parties shall meet on a regular basis for the purpose of consulting with and advising one another regarding certain decisions. In the case of SigmaPharm, such decisions shall include those regarding batch size, manufacturing size, finished goods, Raw Materials and forecasting. Rising shall advise SigmaPharm on such matters as market analysis, market share and pricing. Rising shall also use its best efforts to provide SigmaPharm with prompt notice in the event that there is a price decrease in the marketplace for a particular Product in an amount of at least twenty-five percent (25%).

## 2.2. Collaboration on Product Development and Sales.

2.2.1 **Phases of Product Development and Sales.** The Parties have delineated several Phases in developing, obtaining regulatory approval for, manufacturing and marketing the Product(s) as set forth in **Schedule 8.1** (each referred to individually as a “Phase” and collectively as the “Phases.”) SigmaPharm will provide Rising with written notice of the completion of each of the Phases and Rising will have five (5) days after the receipt of such notice within which to notify SigmaPharm of any termination of this Agreement as provided for below in **Section 12.3.1** and in **Schedule 8.1** of this Agreement.

2.2.2 **Decisions of the Parties; Arbitration.** All decisions of the Parties shall be unanimous, in the exercise of good faith to further the goal of the collaboration. In the event of any dispute, claim, question, or disagreement arising out of or relating to this Agreement or the breach thereof, the Parties shall use Commercially Reasonable Efforts to settle such disputes, claims, questions, or disagreement. To this end, the Parties shall consult and negotiate with each other, in good faith and, recognizing their mutual interests, attempt to reach a just and equitable solution satisfactory to each of the Parties. If they do not reach such resolution within a period of thirty (30) days, then upon notice by either Party to the other, disputes, claims, questions, or differences shall be finally settled by arbitration administered by the American Arbitration Association in accordance with the provisions of its then applicable Commercial Arbitration Rule. Either Party may, however, without inconsistency with this Agreement, seek from a court of competent jurisdiction consistent with the provisions of **Section 14.9** of this Agreement any interim or provisional relief that may be necessary to protect the rights or property of that Party, pending the establishment of the arbitral tribunal (or pending the arbitral tribunal's final determination of the merits of the controversy). Either Party may also seek such interim or provisional relief from the arbitral tribunal. The Parties consent to the jurisdiction of the courts specified in **Section 14.9** of this Agreement for all purposes, including the enforcement of the arbitration agreement and the proceedings, and the entry of a judgment on any award. The costs of arbitration, excluding the Parties' legal fees, shall be borne as directed by the arbitrators.

2.2.3 **Forecasts.** After issuance of the ANDA for each Product, the Parties shall mutually agree upon periodic non-binding forecasts or estimates (each a “Marketing Plan”) setting forth, among other things, the anticipated requirements of the

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Product(s) by Rising, projected dates of the deliveries of the Product(s) by SigmaPharm and projected sales.

3. **RESEARCH AND DEVELOPMENT.**

3.1. **Product Development.** SigmaPharm shall develop the formulation of the Products to be used in clinical studies, to determine if such clinical Products are bioequivalent and therapeutically equivalent to the Reference Products. Such initial clinical studies shall be conducted by Third Party contract research organizations selected by SigmaPharm and under the direction of SigmaPharm (the “**Initial Bioequivalence Study**”) based on pre-existing funds provided by the Parties as set forth in the last sentence of **Section 8.1.1** before the initiation of such study. If such study does not demonstrate that the formulations developed by SigmaPharm are bioequivalent and therapeutically equivalent to the Reference Products, and, if the Parties determine that additional bioequivalence studies (“**Additional Bioequivalence Studies**”) are prudent, then SigmaPharm shall reformulate the Products for use in additional studies to determine if such Products are bioequivalent and therapeutically equivalent to the Reference Products.

3.2. **Conduct of Studies.** SigmaPharm shall use its Commercially Reasonable Efforts to conduct all research and development activities hereunder in accordance with the development plan. Other than certain predevelopment/feasibility/pilot stages of each project which shall not be included in regulatory submissions and are therefore not required to be conducted under strict regulatory rules and guidelines, SigmaPharm represents that all its development activities shall be conducted in accordance with current GMP and all applicable guidelines promulgated by any Regulatory Authority having jurisdiction over the Products in the Territory. SigmaPharm also represents that all its research and development activities which shall be reported and included in the regulatory submission of each Product shall be conducted in accordance with current GLP, GCP and GMP and all applicable guidelines promulgated by any Regulatory Authority having jurisdiction over the Products in the Territory. SigmaPharm also represents that all its research and development activities leading to Regulatory Submissions shall be conducted in accordance with all applicable laws.

4. **REGISTRATION; REGULATORY MATTERS; LICENSE GRANT.**

4.1. **Regulatory Submissions; Regulatory Reporting.**

4.1.1 After the completion of clinical studies demonstrating that the Products are bioequivalent and therapeutically equivalent to the Reference Products and provided that all required stability studies related to the Products have been successfully completed, SigmaPharm shall use Commercially Reasonable Efforts to prepare and file as promptly as practicable the ANDA and other documents that are necessary to obtain Regulatory Approval of the Products in the Territory. SigmaPharm will also have the primary responsibility for responding to questions posed by and interacting with the Regulatory Authorities reviewing the applications for Regulatory Approval of the



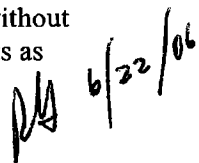
Products. Rising will fully cooperate with SigmaPharm in and provide it with all information necessary for the preparation of applications for Regulatory Approval of the Products and responding to any questions from and providing additional information to those Regulatory Authorities who are reviewing the applications for Regulatory Approval of the Product in the Territory. SigmaPharm shall keep Rising apprised of the status of Regulatory Submissions and Regulatory Approvals, and will make available for inspection only in the case of Licensed Products and also copying in the case of Co-Owned Products all submissions as well as any reports as and when they are issued; provided, however, that SigmaPharm will make available to Rising any and all information related to Regulatory Submissions and Regulatory Approvals if required by Rising to satisfy requests from Regulatory Authorities.

4.1.2 SigmaPharm shall be responsible for all regulatory reporting activities in connection with such Regulatory Approvals, including, without limitation, responding to physician questions regarding the Product and the submission of annual reports and adverse drug experience reports to the appropriate Regulatory Authorities. In accordance with the schedule communicated by SigmaPharm, Rising shall provide SigmaPharm with all information that it reasonably requires to comply with such reporting obligations. Notwithstanding the foregoing, to the extent Rising has or receives any information regarding any adverse drug experience which may be related to the use of any Product, it shall promptly provide SigmaPharm with all such information in accordance with the adverse event reporting procedures established by the Parties.

4.2. **Ownership; License.** Each Product shall be categorized as either a Co-Owned Product or a Licensed Product as indicated on the applicable Schedule and as defined below.

4.2.1 A particular Product shall be referred to as a "Co-Owned Product" in the event that the Parties jointly own all Regulatory Approvals and all applications for Regulatory Approval (including, without limitation, the ANDA and any other registration dossier) for such Product as indicated on **Schedule 4.2.1**. Such ownership rights in such Regulatory Approvals and applications shall not extend to any Know-How of any Party contained in such Regulatory Approval or application, ownership of which shall remain with such Party unless otherwise specifically provided herein.

4.2.2 A particular Product shall be referred to as a "Licensed Product" in the event that SigmaPharm agrees to grant an exclusive license to Rising for the marketing rights of a certain Product in the Territory based on certain licensing fees, sales performance contingencies and royalties on Product sales accepted by Rising that shall be defined on **Schedule 4.2.2** with regards to each Licensed Product. Said Licensed Product, shall be developed by SigmaPharm at its own cost using its proprietary technologies and know-how and shall be owned in its entirety by SigmaPharm which shall retain all marketing rights to such Products and all ownership rights and titles in the Regulatory Approvals and all applications for Regulatory Approval (including, without limitation, the ANDA and any other registration dossier) for all Licensed Products as indicated on **Schedule 4.2.2**.

**4.2.3 Sale of a Product.** In the event that either Party wished to sell the ownership rights to a Co-Owned Product to a Third Party, the Parties shall negotiate in good faith mutually agreeable the terms and conditions of such sale, including, but not limited to, the purchase price to be shared between the Parties in accordance with their respective Percentages.

**4.3. Packaging, Labeling, Marketing and Promotional Materials.** SigmaPharm shall make available to Rising for inspection and copying, in the case of Licensed Products only of only specific portions of, and in the case of Co-Owned Products all, the Regulatory Approvals containing approved Product claims, label indications and other related information necessary for proper Product labeling by Rising. SigmaPharm shall provide Rising with the technical information necessary for the inserts and labels, and for marketing and promotional materials.

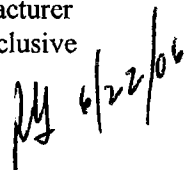
**4.4. License Grant.** SigmaPharm shall grant Rising the right and exclusive license for the License Period to promote, distribute, offer for sale and sell the Licensed Products under Rising's label, trade name and NDC number in the Territory to the end of the applicable License Period, unless sooner terminated pursuant to this Agreement. Upon the expiration of the License Period, either Party may provide the other written notice of termination which shall take effect one (1) year later. If no such termination notice is provided, the License Period shall automatically renew for successive three-year terms thereafter. As consideration for the grant by SigmaPharm of such license, Rising shall pay to SigmaPharm the consideration set forth on the applicable Schedule. Rising shall not be responsible for any costs incurred by SigmaPharm in connection with the development of any Licensed Products, including but not limited to the preparation and filing of related Regulatory Approvals.

## **5. MANUFACTURE AND SUPPLY.**

**5.1. Manufacture and Supply of Products.** Subject to the provisions of this Agreement, SigmaPharm shall manufacture and exclusively supply to Rising and Rising shall exclusively purchase from SigmaPharm all of Rising's requirements of Products for distribution and sale in the Territory. The Parties shall work together to develop and implement, and periodically update, manufacturing forecasts. The Parties shall participate proportionally to each Party's Percentage in the payments related to the procurement of the Raw Materials required to meet the forecasted quantities of each Product provided, however, that such proportional participation in payments has been agreed to in the Specimen Schedule for a particular Product by the Parties. In such case, SigmaPharm shall subtract Rising's portion of the Raw Material cost from the Transfer Price related to a particular Product's commercial supplies.

**5.2. Packaging.** To the extent permitted by applicable law and regulations, SigmaPharm shall be identified on the Product packaging as the exclusive manufacturer of the Products, and Rising shall be identified on the Product packaging as the exclusive labeler/distributor of the Products.

  
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**5.3. Quality Control.**

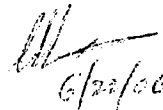
**5.3.1 Specifications.** SigmaPharm shall ensure that all Products manufactured and packaged by it and/or its subcontractors will be manufactured and packaged in accordance with GMP and will conform to the Specifications and the applicable Regulatory Approval(s).

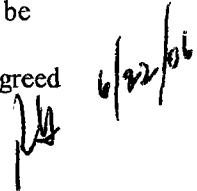
**5.3.2 Changes to Specifications.** Any change in the manufacturing and packaging procedures from that set forth in the Specifications or the applicable Regulatory Approval(s) shall not be implemented without the prior written approval of Rising (which approval shall not be unreasonably withheld) and appropriate Regulatory Approvals, if necessary.

**5.3.3 Testing and Certificate of Analysis.** SigmaPharm shall perform release testing in a manner consistent with GMP testing methods agreed upon by the Parties. SigmaPharm shall provide to Rising a Certificate of Analysis with each shipment of the Products to Rising stating that the Products conform to the Specifications and meet release specifications. SigmaPharm will also retain a copy of the batch records for the applicable lot(s) produced and shall make them available for inspection only by Rising; provided, however, that SigmaPharm shall provide copies of such batch records if reasonably requested by Rising to satisfy inquiries from insurance providers and/or governmental authorities.

**5.3.4 Records and Inspections.** SigmaPharm shall maintain all records relating to the manufacture of the Products necessary to comply with all applicable laws, rules and regulations in each regulatory jurisdiction of sale of the Products and, if different, the regulatory jurisdiction of manufacture of the Products. Specifically, but without limitation, SigmaPharm shall maintain all records and samples reasonably necessary to support GMPs and other regulatory requirements in such regulatory jurisdictions. All records relating to the manufacture of the Product (except quality assurance audit reports for SigmaPharm's internal use only, any documents provided by a Third Party to SigmaPharm under a confidentiality agreement, and SigmaPharm's drug master file for the solid dose form) shall be available for only for inspection in the case of Licensed Products and for inspection and copying in the case of Co-Owned Products, by Rising and its representatives and agents upon reasonable request during normal business hours. All such records shall be maintained for a period of not less than three (3) years or such longer period as may be required by law, rule or regulation. All records relating to the manufacture, stability and quality control of all Products shall be retained for a period of not less than the approved shelf life of the Products as set forth in the Regulatory Approval plus two (2) years.

**5.4. Purchase Orders.** From time to time, Rising shall place purchase orders with SigmaPharm for each of the Products specifying the quantities of the Products desired, and the place(s) to which and the manner and dates by which delivery is to be made; said delivery dates to be no later than forty-five (45) days after the date of acceptance of said purchase order by SigmaPharm unless specified otherwise and agreed

  
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to by both Parties. All purchase orders shall be sent by Rising to SigmaPharm. To the extent the terms of any purchase order or acknowledgments thereof are inconsistent with the terms of this Agreement, the terms of the Specimen Schedule for each Product shall control.

5.5. **Delivery.** Unless specified otherwise and agreed to by both Parties, SigmaPharm shall execute all accepted purchase orders consistent with this Agreement by delivery to the destination recited therein of all ordered quantities of the Products no later than the delivery dates provided in Rising's purchase orders that have been accepted by SigmaPharm. Delivery within ten (10) calendar days of the specified delivery date shall be considered "on time" delivery. Title and risk of loss will pass to Rising when each order of Product is delivered to Rising's designated distribution facility. Rising will promptly notify SigmaPharm, but in any case within seventy-two (72) hours after receipt, of visible defects (e.g., visibly damaged goods or deficient delivery quantities).

5.6. **Purchase Price.** Rising shall purchase from SigmaPharm and SigmaPharm shall sell to Rising Products at a purchase price (the "**Purchase Price**") not to exceed the Transfer Price thereof, and shall pay for the Products within thirty (30) days after the date of the invoice from SigmaPharm (invoices cannot be dated earlier than the date of shipment of such Product to Rising). However, if Rising is unable to sell the Product for which it paid, it shall be entitled to deduct the portion of Purchase Price plus interest allocable to the unsold Products from Net Profits, as set forth above in **Section 1.36**.

5.7. **Discounts and Rebates.** Rising shall be allowed to offer to customers trade discounts, free goods, rebates and other such price concessions as Rising requires to sell the Products; provided that Rising shall obtain SigmaPharm's consent (which shall not be unreasonably withheld) prior to offering any such concessions if such concessions are outside the ordinary course of business; provided, however, that Rising's failure to obtain such consent shall not be considered a breach of this Agreement, including for purposes of **Sections 12 and 13** hereunder. For purposes of this **Section 5.7**, "outside the ordinary course" shall be defined as reducing the price on a Product within one (1) year more than a cumulative total reduction equal to twenty-five (25%) from the original Product pricing offered to the customers.

## 6. **COMMERCIALIZATION.**

6.1. **Trade name.** If needed, as determined by both Parties, the Parties shall market the Products under a trade name which Rising shall have the right to select, subject to the approval of SigmaPharm, which approval will not be unreasonably withheld or delayed. The cost of searching, selecting, registering and enforcing a trade name acceptable to the Parties is reimbursable to Rising and deductible from Net Profits. The Parties shall jointly own all trade names and all applications thereof. Such ownership rights in such trade names and applications shall not extend to any trademarks or trade name owned separately by each of the Parties, including, but not limited to, their respective corporate names and corporate trademarks. Rising shall be responsible for

responding to regulatory inquiries relating to any trade names created hereunder. All Products sold by Rising shall bear the Rising trademark, unless otherwise agreed by the Parties in writing, and shall bear the applicable NDC number and labeler code.

6.2. **Consulting Fees.** The Parties agree to pay the consulting and legal fees of Third Parties not to exceed the amount set forth in **Schedule 6.2** relating to the development of the Products for consulting services that may be rendered from time to time at the request of the Parties. Rising may deduct from Net Profits such fees for such Calendar Quarter.

7. **EXCLUSIVITY.**

The relationship contemplated by this Agreement is intended to and shall be exclusive to the Parties. In furtherance thereof, each Party agrees that it, either alone or via collaboration with or license to any Third Party, shall not develop, manufacture, import, market, sell or promote any product that is directly substitutable to the Reference Product (namely, all FDA rated and pharmaceutically equivalent or bioequivalent to the Reference Products) and has as its active ingredient the Active Ingredient, other than the Products, including both Co-Owned and Licensed.

8. **EXPENSES AND PROFIT SHARING.**

8.1. **Cost Sharing.** It is anticipated that the costs for each Phase of the development, obtaining regulatory approval for, manufacturing, marketing and sale of the Co-Owned Products, including the cost of the Initial Bioequivalence Study, will be as set forth on **Schedule 8.1** and that such costs shall be shared by the Parties in accordance with each Party's Percentage.

8.1.1 For the research and development conducted by SigmaPharm for Co-Owned Products and the regulatory submissions in connection therewith and the related Development Costs, Rising will reimburse SigmaPharm for Rising's Development Cost Percentage of the costs actually incurred or paid by SigmaPharm. Such reimbursement shall be made in accordance with the schedule set forth in **Schedule 8.1** and shall be made within thirty (30) days after receipt by Rising of written notice from SigmaPharm of the completion of each Phase identified on **Schedule 8.1**. In the event that the Parties mutually agree that the Development Costs for a particular Product including those costs related to the Initial Bioequivalence Studies should be shared at the time such costs are incurred by SigmaPharm, Rising shall contribute its Development Cost Percentage of such costs at such time and such amounts shall later be deducted from the amounts Rising is required to reimburse SigmaPharm hereunder.

8.1.2 In connection with the marketing, distribution and sale of the Products, both Co-Owned and Licensed, SigmaPharm and Rising shall share the costs related thereto in accordance with each Party's Percentage. Such costs shall be deducted from gross sales, provided that said costs are not already included in Rising's Fee as defined herein. In the event that such costs exceed gross sales, SigmaPharm shall

reimburse Rising for SigmaPharm's percentage of such costs. In the event that the Parties mutually agree that the Transfer Price for a particular Product is high, the Parties hereby agree that Rising shall be permitted to pay fifty percent (50%) of such Transfer Price when due and the Parties shall agree on the payment schedule for the balance of such Transfer Price, taking into account the anticipated sales cycle.

8.1.3 The Parties agree that each Party shall have no obligation to reimburse the other Party for any portion of expenses incurred by such Party in excess of the anticipated costs unless such excess costs have been approved, in writing, by the other Party prior to the time they are incurred.

8.1.4 SigmaPharm shall be responsible for all costs incurred in connection with the research and development of and obtaining regulatory approval for the Licensed Products; provided, however that pursuant to **Section 4.4** hereof, Rising shall pay SigmaPharm a License Fee, which shall be to cover all of the Development Costs incurred by both Parties of such Licensed Product. Rising shall not be required to pay any additional amounts in connection with the research and development of and obtaining regulatory approval for the Licensed Products.

8.2. **Distribution of Additional Payments.** In the event that the Parties mutually agree to accept payment from a Third Party in exchange for not developing, manufacturing or marketing a Product, such payment shall be shared by the Parties in accordance with each Party's Percentage.

8.3. **Distribution of Net Profits.** Within forty five (45) days after the end of each Calendar Quarter, Rising shall calculate the Net Sales and the Net Profits obtained from the sale of Products during such Calendar Quarter and shall distribute to SigmaPharm, SigmaPharm's Percentage of such Net Profits. Rising shall supply SigmaPharm with a written report setting forth the Net Sales and Net Profits during such Calendar Quarter. If Net Profits related to a Product for any Calendar Quarter is negative, then either Party may invoice the other Party for such amount due to it in accordance with this Agreement and in proportion to each Party's Percentage of such quarterly loss. Such payment shall be made within thirty (30) days of such invoice.

8.4. **Taxes and Withholding.** All payments under this Agreement will be made without any deduction or withholding for or on account of any tax unless such deduction or withholding is required by applicable laws or regulations. If the paying Party is so required to deduct or withhold, such Party will: (i) promptly notify the Party entitled to receive such payment of such requirement; (ii) pay to the relevant authorities the full amount required to be deducted or withheld promptly upon the earlier of determining that such deduction or withholding is required or receiving notice that such amount has been assessed against the Party entitled to receive such payment; and (iii) promptly forward to such other Party an official receipt (or certified copy) or other documentation reasonably acceptable to such other Party evidencing such payment to such authorities. Unless otherwise required by law, each Party shall be responsible for the calculation and payment of its own taxes.



8.5. **Currency.** All amounts payable and calculations hereunder shall be in United States dollars. As applicable, gross sales, Net Sales, gross profits, Net Profits and any expenses incurred by any Party shall be translated into United States dollars using the currency conversion rates set forth in the Wall Street Journal on the date when such payment is due. If, due to restrictions or prohibitions imposed by national authority, payments cannot be made as provided in this **Article 8**, the Parties shall consult with a view to finding a prompt and acceptable solution, and the paying Party will deal with such moneys as the Party entitled to receive such payment may lawfully direct at no additional out-of-pocket expense to the paying Party.

8.6. **Maintenance of Record; Audits.** During the term of this Agreement and for a period of at least seven (7) years after the date of termination of this Agreement, each Party shall keep complete and accurate records of all expenses incurred by it under this Agreement, which expenses are to be reimbursed by one or both of the other Parties. The cost of audits shall be borne by each Party (e.g., the Party requesting an audit pays for their own accountants, and the Party being audited pays for the personnel and overhead costs incurred in "hosting" that audit), provided, however, that in the event such audit by one Party of the other Party's records shows a discrepancy in excess of five percent (5%) of the amount reported by such Party, the Party responsible for the discrepancy will reimburse the auditing Party for the reasonable cost of such audit. Any audit or inspection of books and records by a Party shall be conducted upon reasonable written notice to the other Party, be conducted during normal business hours and will not interfere materially with the business operations of the party being audited or whose books and records are being inspected. In the event that the Products are sold by Rising to any entity that so requests, SigmaPharm hereby agrees that it will make available upon written request of the Secretary of Health and Human Services or the Comptroller General of the United States or any of their duly authorized representatives, copies of this Agreement and any books, documents, records and other data of SigmaPharm that are necessary to certify the nature and extent of costs incurred by such entity for the Products.

## 9. **INTELLECTUAL PROPERTY.**

### 9.1. **Patentable Inventions.**

9.1.1 **Ownership of Patentable Inventions.** SigmaPharm shall own all Inventions made solely by its employees and agents, and all patent applications and patents claiming such Inventions. Rising shall own all Inventions made solely by its employees and agents, and all patent applications and patents claiming such Inventions. All Inventions made jointly by employees or agents of the two Parties and all patent applications and patents claiming such Inventions shall be owned jointly by the Parties. All determinations of inventing under this **Section 9** shall be in accordance with U.S. law

9.1.2 **Patent Procurement.** The Party owning the Invention shall make all decisions with respect to the patent filings and shall have the right to select patent counsel and to take such other actions as are necessary to prepare, file, prosecute and maintain patent protection with regard to the Inventions arising under **Section 9.1.1**.

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With regard to jointly owned Inventions, the Parties shall meet to determine in what countries, if any, patent applications claiming such joint Inventions should be filed. In the event that any of the Parties does not wish to share in the expenses of filing, prosecuting or maintaining such joint Inventions in any country, such Party shall promptly assign or cause to be assigned to the other Party all of its right, title and interest in and to such joint Inventions in the subject country. Thereafter, such joint Invention shall be treated as an Invention solely owned by such other Party within the subject country for all purposes of this Agreement. In the event the Parties desire to proceed with the filing, prosecution and maintenance of such joint invention, such Parties shall share in all expenses related thereto in accordance with each Party's Percentage.

**9.2. Prosecution and Maintenance of Patent Rights.** Each Party shall be responsible for prosecuting and maintaining its own patent applications and patents. Except as otherwise provided in **Section 9.1.2**, all expenses for filing, prosecuting and maintaining a Party's patent applications and patents shall be borne in full by such Party.

**9.3. Cooperation.** Each of the Parties shall execute or have executed by its appropriate employees, representatives, agents and contractors such documents as may be necessary to obtain, perfect or maintain any patent rights filed pursuant to this Agreement. The parties agree to cooperate with one another so far as reasonably necessary with respect to furnishing all information and data in its possession reasonably necessary to obtain or maintain patent rights.

**9.4. Enforcement of Patent Rights.**

**9.4.1 General.** Each Party shall have the sole right but not the obligation, in its own name and at its own expense and benefit to enforce patent rights relating to Inventions which it owns against any Third Party suspected of infringing a claim of such patent right. The Parties owning joint inventions shall meet and jointly determine which Party shall have the right and responsibility to institute, prosecute and control any action or proceeding with respect to the infringement or misappropriation of jointly owned patent rights.

**9.4.2 Cooperation.** In connection with any action taken by either Party against a Third Party to protect or enforce any patent right arising hereunder, the other Party shall, if requested, consult with the Party taking such action, and make available as witnesses its employees or as evidence any materials and/or data reasonably necessary for the furtherance of such action. The expenses in connection with the providing of witnesses and/or the making available of data shall be borne by the Party taking action against the Third Party.

**9.5. Infringement of Third Party Patent Rights.** If any Party is sued for infringement of any Third Party patent arising out of the manufacture, use, sale or importation of a Product in any country of the Territory, the Parties shall promptly meet to discuss the course of action to be taken to resolve or defend any such infringement



litigation. Each Party shall provide the other with such assistance as is reasonably necessary and shall cooperate in the defense of such action.

**9.5.1 Termination Right in the Event of Infringement Litigation.** In the event that the alleged infringement is based upon an allegation that the Products or the process by which Products are manufactured and/or marketed including any allegation relating to the manufacture of raw materials, infringes a Third Party patent and such claim is not dismissed or otherwise resolved to the satisfaction of a Party within ninety (90) days following written notice of the claim, then that Party shall have the right to terminate immediately its participation in this Agreement by notice to the other Party. Each Party's right of termination shall expire if not exercised before final resolution of such claim. A termination pursuant to this **Section 9.5.1** shall be deemed to be a termination for cause pursuant to **Section 12.2** of this Agreement only if the Third Party claiming infringement prevails via a settlement or a final and non-appealable court decision over the Non-Terminating Party. In any other case, the Terminating Party shall automatically waive any and all rights to the Product and shall collaborate in good faith and by using its Commercially Reasonable Efforts to assist the Non-Terminating Party in continuing the exploitation of the Product.

#### **10. CONFIDENTIALITY.**

**10.1. Confidentiality.** Except to the extent expressly authorized by this Agreement or otherwise agreed in writing, the Parties agree that, during the term of this Agreement and for five (5) years following expiration or termination of this Agreement, each Party (the "**Receiving Party**") receiving hereunder any written information marked as "confidential" at the time of its disclosure or any verbal information a written summary of which is marked "confidential" and delivered to the Receiving Party within thirty (30) days following disclosure (collectively, "**Confidential Information**"), of any other Party (the "**Disclosing Party**") shall keep such Confidential Information confidential and shall not publish or otherwise disclose or use such Confidential Information for any purpose other than as provided for in this Agreement except for Confidential Information that the Receiving Party can establish:

(a) was already known to the Receiving Party (other than under an obligation of confidentiality) at the time of disclosure by the Disclosing Party and such Receiving Party has documentary evidence to that effect;

(b) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the Receiving Party;

(c) became generally available to the public or otherwise part of the public domain after its disclosure or development, as the case may be, and other than through any act or omission of a Party in breach of this confidentiality obligation;

(d) was disclosed to that Party, other than under an obligation of confidentiality, by a Third Party who had no obligation to the Disclosing Party not to disclose such information to others;

(e) was independently discovered or developed by or on behalf of the Receiving Party without the use of the Confidential Information belonging to the Disclosing Party and the Receiving Party has documentary evidence to that effect. The Parties acknowledge and agree that any Confidential Information of a Party disclosed during discussion and negotiation of this Agreement prior to commencement of the term of this Agreement shall be entitled to protection pursuant to this **Section 10.1**.

#### **10.2. Authorized Disclosure and Use.**

**10.2.1 Disclosure.** Notwithstanding the foregoing **Section 10.1**, each Party may disclose Confidential Information belonging to the other Party to the extent such disclosure is reasonably necessary to:

- (a) file or prosecute patent applications claiming Inventions arising under this Agreement (but only with the prior written consent of the Disclosing Party),
- (b) prosecute or defend litigation,
- (c) exercise rights hereunder provided such disclosure is covered by terms of confidentiality similar to those set forth herein, and
- (d) comply with applicable governmental laws and regulations.

In the event the Receiving Party shall deem it necessary to disclose, pursuant to this **Section 10.2.1**, Confidential Information belonging to the Disclosing Party, the Receiving Party shall, to the extent possible, give reasonable advance notice of such disclosure to the Disclosing Party and take reasonable measures to ensure confidential treatment of such Confidential Information.

#### **11. REPRESENTATIONS AND WARRANTIES.**

**11.1. Representations and Warranties of Each Party.** Each Party hereby represents and warrants to the other Party that:

- (a) it is a corporation or entity duly organized and validly existing under the laws of the state or other jurisdiction of its incorporation or formation;
- (b) the execution, delivery and performance of this Agreement by such Party has been duly authorized by all requisite corporate action and does not require any shareholder action or approval;
- (c) it has the power and authority to execute and deliver this Agreement and to perform its obligations hereunder;

(d) the execution, delivery and performance by such Party of this Agreement and its compliance with the terms and provisions hereof does not and will not conflict with or result in a breach of any of the terms and provisions of or constitute a default under: (i) a loan agreement, guaranty, financing agreement, agreement affecting a product or other agreement or instrument binding or affecting it or its property; (ii) the provisions of its charter or operative documents or bylaws; or (iii) any order, writ, injunction or decree of any court or governmental authority entered against it or by which any of its property is bound;

(e) it shall at all times comply with all applicable material laws and regulations relating to its activities under this Agreement; and

(f) it has the full right, power and authority to grant all of the right, title and interest in the licenses, if any, granted to the other Party under this Agreement.

**11.2. Additional Representations and Warranties of SigmaPharm.** In addition to the representations and warranties made by SigmaPharm under **Section 11.1** above, SigmaPharm further represents and warrants that:

(a) it shall use Commercially Reasonable Efforts in carrying out its responsibilities under the Agreement, such efforts to be determined, in part, by the implementation of the Development Plans, Sale Forecasts and Marketing Plans;

(b) all Products manufactured and packaged by it hereunder shall be manufactured, stored and shipped in accordance with all GMP's as applicable and all other applicable material laws, rules, regulations or governmental or regulatory requirements in effect at the time of manufacture, storage and shipping of Product, namely, the Product conforms to the Specifications, is merchantable (e.g., has no manufacturing defect) and is not adulterated; shall be in compliance with the ANDA for the Product and otherwise with the requirement of the Act; not be misbranded within the meaning of the Act and regulations issues thereunder, or any state law substantially similar to the Act; be transportable and storable in the ordinary manner in which similar such products are transported and stored; and conform to all applicable standards and regulations promulgated by any and all governmental and regulatory authorities, including without limitation the FDA, the FTC, and the various state, municipal, territorial and local governmental and regulatory authorities, as well as any standards customary and accepted in the industry;

(c) that all precautions reasonably necessary and customary in the industry shall be taken in manufacturing, testing, packaging, labeling and handling the Products to ensure the quality, safety and fitness of the Products;

(d) that each Unit of the Products shall bear an expiration date of no less than eighteen (18) months following the date of its delivery; and

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(e) based on its preliminary analysis, SigmaPharm believes that Commercially Reasonable Efforts will result in the ability to develop and manufacture, and obtain regulatory approval for, the Products.

**11.3. Additional Representations and Warranties of Rising.** In addition to the representations and warranties made by Rising under **Section 11.1** above, Rising further represents and warrants that:

(a) it shall use Commercially Reasonable Efforts in carrying out its responsibilities under the Agreement, such efforts to be determined, in part, by the implementation of the Marketing Plan;

(b) it shall comply with all requirements of the PDMA, FDA regulations and applicable state law requirements regarding the marketing, sale and distribution of Product including, without limitation, compliance with any applicable law related to approved use and off-label use restrictions of the Products;

(c) all Products distributed by it hereunder shall be treated, stored and shipped in accordance with all GMPs as applicable and all other applicable material laws, rules, regulations or governmental or regulatory requirements in effect at the time of storage and shipping of Product, namely, the Product is not adulterated; shall be transportable and storable in the ordinary manner in which similar such products are transported and stored; and conform to all applicable material standards and regulations promulgated by any and all governmental and regulatory authorities, including without limitation the FDA, the FTC, and the various state, municipal, territorial and local governmental and regulatory authorities;

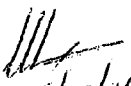

(d) it shall maintain adequate warehousing, distribution facilities, documentation and personnel to provide reasonable distribution, staffing for customer service, billing, marketing and accounting with respect to the Products.

**11.4. Representation by Legal Counsel.** Each Party hereto represents that it has been represented by legal counsel in connection with this Agreement and acknowledges that it has participated in the drafting hereof. In interpreting and applying the terms and provisions of this Agreement, the Parties agree that no presumption shall exist or be implied against the Party which drafted such terms and provisions.

**11.5. No Inconsistent Agreements.** Neither Party has in effect and, after the Effective Date neither Party shall enter into, any oral or written agreement or arrangement that would be inconsistent with its obligations under this Agreement.

## **12. TERM AND TERMINATION.**

**12.1. Term.** This Agreement shall become effective on the Effective Date and continue until terminated by either Party as provided for below. In the event that all of the individual Products and related Schedules have been terminated, either Party may

  
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terminate this Agreement by providing the other Party with thirty (30) days' prior written notice.

**12.2. Termination for Cause.** This Agreement, as it relates to a particular Product, may be terminated effective immediately by written notice by either Party at any time during the Term of this Agreement (i) for material breach by the other Party, which breach remains uncured for ninety (90) days measured from the date written notice of such breach is given to the breaching Party, provided, however, that if such breach is not cured within the stated period and the breaching Party uses diligent good faith efforts to cure such breach, the stated period will be extended by an additional ninety (90) days; (ii) if the other Party makes any assignment of assets or business for the benefit of creditors, or if a trustee or receiver is appointed to administer or conduct the business or affairs of the other Party, or if the other Party is adjudged in any legal proceeding to be either voluntary or involuntary bankrupt which remains undismissed for a period of thirty (30) days or more; and (iii) in accordance with the provisions of **Section 9.5.1** (Termination Right in the Event of Infringement Litigation).

**12.3. Termination other than for Cause or Mutual termination.**

**12.3.1 During Development Phases.** Prior to issuance of an ANDA for a Product, either Party may terminate this Agreement with respect to such Product during or at the conclusion of each of the Phases identified on **Schedule 8.1** upon written notice to the other Party.

**12.3.2 During Commercialization.** After issuance of an ANDA for a Product, in the event that either Party desires to terminate this Agreement with respect to such Product other than by reason of **Section 12.2** (cause) or **Section 12.4** (mutual termination), such Party (the "**Withdrawing Party**") shall give the other Party (the "**Remaining Party**") not less than ninety (90) days prior written notice thereof (the "**Withdrawal Notice**"), such termination to be effective at the conclusion of such ninety (90) day period.


**12.4. Mutual Termination.** The Parties may jointly agree in writing, at any time, to discontinue or terminate the Products.

**12.5. Effect of Termination.**

**12.5.1 Mutual Termination.** In the event that the Agreement is terminated by reason of mutual termination, the effect of such termination shall be as set forth in the agreement between the Parties relating to such termination.

**12.5.2 During Development Phases.** In the event that either Party terminates this Agreement prior to issuance of an ANDA for a Product other than by reason of **Section 12.2** (cause) or **Section 12.4** (mutual termination), the terminating Party shall be liable to pay or reimburse the non-terminating Party as provided for in **Section 8.1** and **Schedule 8.1**. In addition, in such event, the terminating party shall not

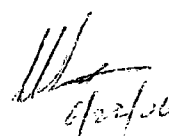
  
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pursue the development, manufacture, marketing, distribution or sale of such Product for a period of five (5) years after the effective date of such termination.

**12.5.3 Generally.** If either Party terminates this Agreement other than by reason of **Section 12.4** (mutual termination), the Party not in breach of the Agreement (the “**Continuing Party**”) or the Remaining Party, as the case may be, may continue to develop, market and sell the Products and shall have the right to purchase the rights of the terminating Party (the “**Non-Continuing Party**”) or the Withdrawing Party, as the case may be, in and to the Products. The Non-Continuing Party or the Withdrawing Party, as the case may be, shall contemporaneously assign or license, as applicable, to the Continuing Party or the Remaining Party, as the case may be, the Non-Continuing Party’s or Withdrawing Party’s, as the case may be, proprietary rights needed by the Continuing Party or the Remaining Party, as the case may be, to continue to develop (or have made), import, market, distribute and sell the Products, including any SigmaPharm Technology and Rising Technology, as the case may be. The assigned or licensed rights, as applicable, shall include, without limitation and as appropriate, Regulatory Approvals (including the ANDA), the trade names and the manufacturing rights, the good will related to the Products (approved and in various stages of development), accounts receivable, inventory and cash on hand from the sale of the Products. The purchase price of such rights shall be one dollar (\$1.00) or as stipulated by the Parties in the Specimen Schedule for the Product. The purchased rights shall be held as agreed by the Continuing Party or Remaining Party, as the case may be, or failing agreement, shall be held on a joint basis. The Non-Continuing Party or Withdrawing Party, as the case may be, shall provide the following paid up, perpetual licenses and shall make the following payments to the Continuing Party or Remaining Party, as the case may be:

(a) **By SigmaPharm.** Except if otherwise specified in the Specimen Schedule relevant to a Product, if SigmaPharm is the Non-Continuing Party or Withdrawing Party, as the case may be, then subject to the terms and conditions of this Agreement, it shall grant to Rising an exclusive license in and to the SigmaPharm Technology (provided that Rising shall represent, warrant and covenant to SigmaPharm that it shall not use SigmaPharm’s Technology for the development and exploitation of any other products), to the extent necessary for Rising to perform SigmaPharm’s obligations and exercise its rights under this Agreement, including, without limitation, any and all obligations and rights that need to be performed or exercised by or on behalf of SigmaPharm to develop, make, have made, use, import, market, offer for sale or sell Products in the Territory in accordance with this Agreement. In the event that Rising purchases SigmaPharm’s interest hereunder, SigmaPharm agrees that it shall continue manufacturing the Products for Rising based on the same business relationship (namely, Transfer Price, Percentage of Net Profits, etc.) defined in this Agreement and the Specimen Schedule relevant to the particular purchased, terminated or withdrawn Product, as the case may be, for a period of eighteen (18) months following the effective date of the purchase hereunder, and shall use Commercially Reasonable Efforts to assist Rising and cause the ANDA to be placed with another manufacturer. During such eighteen (18) month period, SigmaPharm shall not develop, manufacture, import, market, sell or promote any product that is directly substitutable to those Products being manufactured pursuant to the preceding sentence.




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(b) **By Rising.** Except if otherwise specified in the Specimen Schedule relevant to a Product, if Rising is the Non-Continuing Party or Withdrawing Party, as the case may be, then subject to the terms and conditions of this Agreement, Rising shall grant to SigmaPharm an exclusive license in and to the Rising Technology (provided that SigmaPharm shall represent, warrant and covenant to Rising that it shall not use Rising's Technology for the development and exploitation of any other products), to the extent necessary for SigmaPharm to perform Rising's obligations and exercise its rights under this Agreement, including, without limitation, any and all obligations and rights that may need to be performed or exercised by or on behalf of Rising to develop, make, have made, use, import, market, offer for sale or sell Products in the Territory in accordance with this Agreement. In the event that SigmaPharm purchases Rising's interest hereunder, Rising agrees that it shall continue distributing, marketing and selling the Products for SigmaPharm based on the same business relationship (namely, Rising's Fee, Percentage of Net Profits, etc.) defined in this Agreement and the Specimen Schedule relevant to the particular purchased, terminated or withdrawn Product, as the case may be, for a period of eighteen (18) months following the effective date of the purchase hereunder, and shall use Commercially Reasonable Efforts to assist SigmaPharm and cause the NDC numbers and Rising's Product Label rights to be transferred to SigmaPharm or to a Third Party of SigmaPharm's choice. During such eighteen (18) month period, Rising shall not develop, manufacture, import, market, sell or promote any product that is directly substitutable to those Products being distributed, marketed and sold pursuant to the preceding sentence.

(c) **License Limitations.** This Agreement shall not be construed as granting to the Continuing Party or remaining Party, as the case may be, as a result of this Agreement, any right, title or interest in or to, the SigmaPharm Technology or the Rising Technology, as the case may be, for use in connection with pharmaceutical products other than the Products.

12.6. **Reports to Continue.** Notwithstanding anything to the contrary, except in the event of default, Rising shall continue to provide SigmaPharm with the reports provided for in **Section 8.3** above until each and every Product has been sold.

### 13. INDEMNIFICATION; LITIGATION AND INSURANCE.

13.1. **Litigation.** The expenses incurred in litigating any claims or actions brought by a Third Party (including reasonable legal fees and the payment of damages and expenses to a Third Party) shall be shared by the Parties in accordance with each Party's Percentage to the extent such expenses are not covered by or exceed the limits of the insurance to be purchased under **Section 13.6** hereof. All recoveries obtained from Third Parties in connection with any such actions shall be shared by the Parties in accordance with each Party's Percentage, whether such recoveries arise by way of settlement or otherwise. Any losses or expenses payable to Third Parties shall be shared by the Parties in accordance with each Party's Percentage, to the extent such losses or expenses are not covered by or exceed the limits of the insurance to be purchased under **Section 13.6** hereof; provided, however, to the extent such losses or expenses are solely

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the result of the breach by one Party of its representations, warranties or covenants herein, then the breaching Party shall be responsible for such loss or expense. Notwithstanding the foregoing and provided that the Parties to this Agreement have not authorized or changed this Section to the contrary in a separate Product-specific instrument or Schedule, each Party to this Agreement shall be solely responsible for: (i) defending against; and (ii) bearing all expenses (including, without limitation, damages payable to a Third Party) incurred in connection with any actions which: (a) are based upon the claims of a Third Party that the methods or processes utilized by either Party to this Agreement in manufacturing or marketing the Product as the case may be, infringe the intellectual property rights of such Third Party; or (b) arise due to the manufacturing or marketing of the Product outside of the applicable Regulatory Approvals. In connection with the Licensed Products, SigmaPharm is responsible for assuring the quality and correctness of the related ANDA, and thus is responsible for and shall bear all expenses (including, without limitation, damages payable to a Third Party) incurred in connection with claims or actions relating to the approval of such ANDA or related Regulatory Approvals. Each Party shall cooperate in good faith with the other Party to resolve any claim made by a Third Party. Each Party will promptly inform the other Party of any threatened or impending actions of any kind, including, but not limited to, any FDA enforcement action against the Products (e.g., involuntary recall, Product seizure) or the ANDA holder. Rising will arrange for, collect and ship to SigmaPharm all Products which are no longer marketable (due to, e.g., FDA mandated regulatory enforcement action, expired dating or a voluntary Product recall). In so doing, Rising will comply with applicable law, including the PDMA. Rising, with SigmaPharm's consent (not to be unreasonably withheld), may create such reserves for Litigation Expenses and related damages as the Parties may deem to be reasonable from Net Profits that would otherwise be distributed pursuant to **Section 8.3** of this Agreement, place such amounts in escrow for the duration of such litigation and use such reserves to pay Litigation Expenses and related damages. For the avoidance of doubt, except as set forth in **Sections 13.2** and **13.3**, any Liabilities related to a product liability claim based on an alleged defect in the Active Ingredient shall be shared by the Parties in accordance with each Party's Percentage.

**13.2. Indemnification by SigmaPharm.** SigmaPharm shall indemnify and hold harmless Rising and its respective directors, officers, employees and agents, from and against all losses, liabilities, damages and expenses, including reasonable attorneys' fees and costs (collectively "**Liabilities**") resulting from any claims, demands, actions or other proceedings by any Third Party arising from: (i) the material breach of any representation, warranty or covenant by SigmaPharm under this Agreement; (ii) the purchase or manufacture by SigmaPharm of any raw materials required for the development and/or manufacture of Products (other than patent claims which are governed by **Section 9.5**); (iii) the manufacture, negligent handling or storage by SigmaPharm or its Affiliates of Products; (iv) the potential infringement of any of the Regulatory Approvals of a Licensed Product or any of the applications for Regulatory Approval of a Licensed Product of the intellectual property rights of a Third Party (provided that no amendment to the contrary exists in a Product-specific schedule); or (v)

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the potential infringement of any of the methods or processes utilized by SigmaPharm in manufacturing any Product of the intellectual property rights of such Third Party (provided that no amendment to the contrary exists in a Product-specific schedule); provided, however, that SigmaPharm shall not be obligated to indemnify or hold harmless Rising to the extent such Liabilities arise from: (a) product liability claims related to the Active Ingredient, which Liabilities shall be shared by the Parties in accordance with each Party's Percentage; or (b) the negligence or willful misconduct of Rising.

**13.3. Indemnification by Rising.** Rising shall indemnify and hold harmless SigmaPharm and their respective members, officers, employees, and agents, from and against all Liabilities resulting from any claims, demands, actions or other proceedings by any Third Party arising from: (i) the material breach of any representation, warranty or covenant by Rising under this Agreement; (ii) the marketing, sale and distribution by Rising of Products; (iii) the potential infringement of any of the methods or processes utilized by Rising in marketing any Product of the Intellectual Property Rights of a Third Party (provided that no amendment to the contrary exists in a Product-specific schedule and provided further that marketing will not include any issues related to labeling); or (iv) the negligent handling or storage by Rising or its Affiliates of Products, provided, however, that Rising shall not be obligated to indemnify or hold harmless SigmaPharm to the extent such Liabilities arise from: (a) product liability claims related to the Active Ingredient, which Liabilities shall be shared by the Parties in accordance with each Party's Percentage; or (b) the negligence or willful misconduct of SigmaPharm.

**13.4. Conditions to Indemnification.** The obligations of the indemnifying Party under **Sections 13.2 and 13.3** are conditioned upon the delivery of written notice by the indemnified Party to the indemnifying Party of any potential liability promptly after the indemnified Party or parties become aware of such potential liability, provided, however, that the failure to give such notice promptly shall not impair a Party's right to indemnification under this **Section 13** unless the delay in providing such notice has a material adverse effect on the ability of the indemnifying Party to defend against such liability. The indemnifying Party shall have the right to assume the defense of any suit or claim relating to the liability if it has assumed responsibility for the suit or claim in writing; however, if in the reasonable judgment of the indemnified Party, such suit or claim involves an issue or matter which could have a material adverse effect on the business operation or assets of the indemnified Party, the indemnified Party may waive its rights to indemnity under this Agreement and control the defense or settlement thereof; provided, further, however, that in the event such suit or claim involves an issue or matter related to the intellectual property rights of the indemnifying party, the indemnified party may only waive its rights to indemnity and control the defense or settlement thereof after the indemnifying party has failed to promptly and in good faith undertake the necessary actions to defend such suits or claims, but in no event shall any such waiver be construed as a waiver of any rights such indemnified Party may have against any Party hereunder or any Third Party at law or in equity. If the indemnifying Party defends the suit or claim, the indemnified Party may participate in (but not control) the defense thereof at its sole cost and expense.

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13.5. **Settlements.** Neither of the Parties may settle a claim or action related to a Liability without the consent of the other Party, such consent not to be unreasonably withheld, if such settlement would impose any monetary obligation on the other Party, or would require the other Party to submit to an injunction or otherwise limit the other Party's rights under this Agreement. Any payments made by a Party to settle any such claim or action shall be at its own costs and expense, except in the event such payment was made with the prior written consent of an indemnifying Party, in which case such payment shall be subject to the obligations of the Parties as set forth in **Sections 13.2 and 13.3.**

13.6. **Insurance.** Prior to the earlier of sixty (60) days from the date hereof and the first day of the first Initial Bioequivalence Study, each Party shall obtain and maintain at its own expense insurance coverage, including Product Liability Insurance, on the Products with liability limitations of not less than five million dollars (\$5.0 Million) per occurrence and in the aggregate. Each Party shall deliver a Certificate of Insurance to the other Party evidencing the existence of such insurance. Each Party shall be named as additional insured on the policy obtained by the other Party and such policy, without limiting such Party's indemnification obligations under this **Section 13**, shall provide contractual liability coverage for such Party's indemnification obligations hereunder. Each Party agrees that such Party's insurance shall always be the primary insurance in connection with such Party's indemnification obligations hereunder.


#### 14. MISCELLANEOUS.

14.1. **Assignment/Sale, etc.** Neither Party may sell, assign, pledge, hypothecate or otherwise dispose of its interests under this Agreement without the consent of the other Party. Neither this Agreement nor any interest hereunder shall be assignable by any Party without the prior written consent of the other Party. Notwithstanding the foregoing, each Party shall be permitted to assign this Agreement to (i) any successor by merger or upon sale of all or substantially all of the assets to which this Agreement relates and/or (ii) an Affiliate; provided, however, that in the case of clause (ii), the assigning Party agrees to remain liable for the obligations hereunder. This Agreement shall be binding upon the successors and permitted assigns of the Parties and the name of a Party appearing herein shall be deemed to include the names of such Party's successors and permitted assigns to the extent necessary to carry out the intent of this Agreement. Any assignment not in accordance with this **Section 14.1** shall be void.

14.2. **Further Actions.** Each Party agrees to execute, acknowledge and deliver such further instruments, and to do all such other acts, as may be necessary or appropriate in order to carry out the purposes and intent of the Agreement.

14.3. **Force Majeure.** Neither Party shall be liable to the other for delay or failure in the performance of the obligations on its part contained in this Agreement if and to the extent that such failure or delay is due to circumstances beyond its control which it could not have avoided by the exercise of reasonable diligence. It shall notify the other Party promptly should such circumstances arise, giving an indication of the likely extent

  
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and duration thereof, and shall use all Commercially Reasonable Efforts to resume performance of its obligations as soon as practicable, provided, however, that neither Party shall be required to settle any labor dispute or disturbance.

**14.4. Correspondence and Notices.**

**14.4.1 Ordinary Notices.** Correspondence, reports, documentation, and any other communication in writing between the Parties in the course of ordinary implementation of this Agreement shall be delivered by hand, sent by facsimile transmission (receipt verified), or by airmail to the employee or representative of the other Party who is designated by such other Party to receive such written communication.

**14.4.2 Extraordinary Notices.** Extraordinary notices and other communications hereunder (including, without limitation, any notice of force majeure, breach, termination, change of address, exercise of rights to negotiate additional agreements, etc.) shall be in writing and shall be deemed given if delivered personally or by facsimile transmission (receipt verified), mailed by registered or certified mail (return receipt requested), postage prepaid, or sent by nationally recognized express courier service, to the Parties at the following addresses (or at such other address for a Party as shall be specified by like notice, provided, however, that notices of a change of address shall be effective only upon receipt thereof):

All correspondence to Rising shall be addressed as follows:

Rising Pharmaceuticals, Inc.  
3 Pearl Court  
Suite A/B  
Allendale, New Jersey 07401  
Attn: Mr. Ronald Gold, President  
Fax: 201-961-1234

All correspondence to SigmaPharm shall be addressed to the following locations:

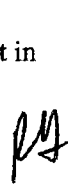
SigmaPharm Laboratories, LLC  
860 Town Center Drive  
Langhorne, PA 19047  
Attn: Spiro Spireas, Ph.D., Chairman & CEO  
Fax: : (215) 891-0775

SigmaPharm Laboratories, LLC  
3375 Progress Drive  
Bensalem, PA 19020  
Attn: Spiro Spireas, Ph.D., Chairman & CEO  
Fax:

**14.5. Amendment.** No amendment, modification or supplement of any provision of this Agreement shall be valid or effective unless made in writing and signed by a duly authorized officer of each Party.

**14.6. Waiver.** No provision of the Agreement shall be waived by any act, omission or knowledge of a Party or its agents or employees except by an instrument in

  
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writing expressly waiving such provision and signed by a duly authorized officer of the waiving Party.

**14.7. Severability.** If any clause or portion thereof in this Agreement is for any reason held to be invalid, illegal or unenforceable, the same shall not affect any other portion of this Agreement, as it is the intent of the Parties that this Agreement shall be construed in such fashion as to maintain its existence, validity and enforceability to the greatest extent possible. In any such event, this Agreement shall be construed as if such clause or portion thereof had never been contained in this Agreement, and there shall be deemed substituted thereof such provision as will most nearly carry out the intent of the Parties as expressed in this Agreement to the fullest extent permitted by applicable law unless doing so would have the effect of materially altering the rights and obligations of the Parties in which event this Agreement shall terminate and all the rights and obligations granted to the Parties hereunder shall cease and be of no further force and effect.


**14.8. Descriptive Headings.** The descriptive headings of this Agreement are for convenience only, and shall be of no force or effect in construing or interpreting any of the provisions of this Agreement.

**14.9. Governing Law; Jurisdiction.** This Agreement shall be governed by and interpreted in accordance with the substantive laws of the State of New Jersey, without regard to conflict of law principles thereof, and the Parties consent to and agree to submit to the jurisdiction of the courts of the State of New Jersey, state and federal, with respect to actions and proceedings relating to or arising out of this Agreement.

**14.10. Entire Agreement of the Parties.** This Agreement constitutes and contains the complete, final and exclusive understanding and agreement of the Parties and cancels and supersedes any and all prior negotiations, correspondence, understandings and agreements, whether oral or written, among the Parties respecting the subject matter hereof and thereof. The Schedules to this Agreement shall be deemed to be an integral part hereof, and schedules or exhibits to such Schedules shall be deemed to be an integral part thereof. If there is any direct conflict between the provisions of this Agreement and any Schedules, the provisions of the applicable Schedule shall be determinative.

**14.11. Independent Contractors.** Each Party is an independent contractor under this Agreement. Nothing herein contained shall be deemed to create an employment, agency, joint venture or partnership relationship between any of the Parties hereto or any of their agents or employees, or any other legal arrangement that would impose liability upon one Party for the act or failure to act of either of the other Parties. No Party shall have any express or implied power to enter into any contracts or commitments or to incur any liabilities in the name of, or on behalf of, any other Party, or to bind any other Party in any respect whatsoever.


  
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14.12. **Debarment.** Each Party agrees that it will not use, in any capacity, in connection with any of its obligations to be performed under this Agreement any individual who has been debarred under the Act or the Generic Drug Enforcement Act.

14.13. **Survival.** The representations and warranties set forth in **Sections 8, 10, 12, 13 and 14** shall survive the termination of this Agreement.

14.14. **Counterparts.** This Agreement may be executed in any number of counterparts, each of which need not contain the signature of more than one Party but all such counterparts taken together shall constitute one and the same agreement.

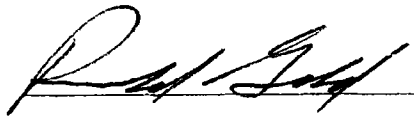
  
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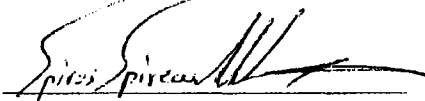
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**IN WITNESS WHEREOF**, duly authorized representatives of the Parties have duly executed this Agreement to be effective as of the Effective Date.

Rising Pharmaceuticals, Inc.

SigmaPharm Laboratories, LLC

By: 

By:  6/22/06

Name: RONALD GOLD

Name: SPIRO SPIREAS, PH.D.

Title: PRESIDENT

Title: CHAIRMAN & CEO

**AMENDMENT TO MASTER PRODUCT DEVELOPMENT AND  
COLLABORATION AGREEMENT by and between Rising Pharmaceuticals, Inc.  
("Rising") and SigmaPharm Laboratories, LLC ("SigmaPharm"), dated as of  
June 22, 2006 (the "Agreement")**

**WHEREAS**, Rising and SigmaPharm wish to clarify the Agreement by amending certain provisions of the Agreement.

NOW, THEREFORE, in consideration of the mutual promises contained in this Amendment, and their continued performance under the Agreement, Rising and SigmaPharm agree as follows:

- 1) Section 1.43 of the Agreement is amended to substitute the phrase "Metropolitan Statistical Area" for the phrase "Standard Metropolitan Statistical Area."
- 2) THIS PARAGRAPH LEFT INTENTIONALLY BLANK.
- 3) Section 1.52 of the Agreement is deleted and replaced in its entirety by the following:

**1.52 "Rising's Fee"** shall be calculated on a per Product basis as follows: (i) a distribution fee for the Product which shall include distribution, shipping, warehousing, rebate and chargeback management, accounting, customer service, and inventory financing (where applicable) expenses and shall be equal to the following: in the event that annual Net Sales of all Products under all Product Schedules are less than \$10 Million, four percent (4%) of the annual Net Sales of the subject Product; in the event that annual Net Sales of all Products under all Product Schedules are greater than \$10 Million but less than \$20 Million, three point five percent (3.5%) of the annual Net Sales of the subject Product; in the event that annual Net Sales of all Products under all Product Schedules are greater than \$20 Million but less than \$30 Million, three (3%) of the annual Net Sales of the subject Product; in the event that annual Net Sales of all Products under all Product Schedules are greater than \$30 Million but less than \$50 Million, two point five percent (2.5%) of the annual Net Sales of the subject Product; in the event that annual Net Sales of all Products under all Product Schedules are greater than \$50 Million but less than \$100 Million, two percent (2%) of the annual Net Sales of the subject Product; and in the event that annual Net Sales of all Products under all Product Schedules are greater than \$100 Million, one point five percent (1.5%) of the annual Net Sales of the subject Product; plus (ii) a marketing and sales fee for the Product which shall include travel, tradeshow and other sales-related expenses, sales administration, and sales incentives and shall be equal to the following: in the event that annual Net Sales of all Products under all Product Schedules are less than \$10 Million, four percent (4%) of the annual Net Sales of the

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subject Product; in the event that annual Net Sales of all Products under all Product Schedules are greater than \$10 Million but less than \$20 Million, three point five percent (3.5%) of the annual Net Sales of the subject Product; in the event that annual Net Sales of all Products under all Product Schedules are greater than \$20 Million but less than \$30 Million, three (3%) of the annual Net Sales of the subject Product; in the event that annual Net Sales of the all Products under all Product Schedules are greater than \$30 Million but less than \$50 Million, two point five percent (2.5%) of the annual Net Sales of the subject Product; in the event that annual Net Sales of all Products under all Product Schedules are greater than \$50 Million but less than \$100 Million, two percent (2.%) of the annual Net Sales of the subject Product; and in the event that annual Net Sales of all Products under all Product Schedules are greater than \$100 Million, one point five percent (1.5%) of the annual Net Sales of the subject Product.

The Rising Fee used for each Product for the calculation of Net Profits for the first three Calendar Quarters of a calendar year shall be based upon Rising's estimate, subject to SigmaPharm consent which shall not be unreasonably withheld, of annual Net Sales for all Products under all Product Schedules for that calendar year. If, at the end of the calendar year, it is discovered that Rising's estimate of annual Net Sales for all Products under all Product Schedules was not correct, the appropriate adjustment will be made in the distribution of Net Profits pursuant to Section 8.3 of the Agreement following the 4<sup>th</sup> Quarter of that calendar year. As used in this Section 1.56, the term "calendar year" means the period starting on January 1 of a year and ending on December 31 of that same year.

4) The terms "Schedule," "Product Schedule," and "Specimen Schedule" in the Agreement (including any Amendment to the Agreement) have the same meaning unless specifically indicated otherwise in the Agreement or the Amendment.

5) The last sentence of Section 14.10 is deleted and replaced in its entirety by the following:

If there is a conflict between the provisions of this Agreement and the provisions of a Product Schedule, the provisions of the Product Schedule shall control and be determinative for the Product which is identified and described in that Schedule.

6) Section 14.13 of the Agreement is deleted and replaced in its entirety by the following:

**14.13. Survival.** All representations, warranties, covenants, and promises of the Parties and the terms and conditions of Sections 8, 10, 12, 13, and 14, including all subsections of



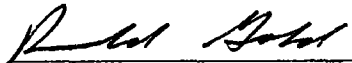
those Sections, shall survive the termination of a Product Schedule and/or this Agreement, notwithstanding any language in the Agreement or a specific Product Schedule to the contrary.

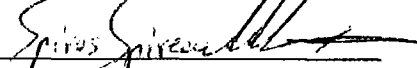
- 7) This Amendment applies to all Products listed on any Schedule to the Agreement and shall be effective as to all Products as of the Effective Date.
- 8) Capitalized terms used in this Amendment have the same meaning as given those terms in the Agreement.
- 9) Except as expressly modified by this Amendment, the Agreement is not changed in any respect by this Amendment.
- 10) The Effective Date of this Amendment is September 4, 2008.

IN WITNESS WHEREOF, Rising and SigmaPharm, by and through their duly authorized representatives, have signed this Amendment intending to be fully bound.

Rising Pharmaceuticals, Inc.

SigmaPharm Laboratories, LLC

By: 

By: 

Name: RONALD GOLD

Name: SPIRO SPIREAS, Ph.D

Title: PRESIDENT

Title: CHAIRMAN & CEO

Date: Sept. 4<sup>th</sup> 2008

Date: Sept. 4, 2008

**AMENDMENT TO MASTER PRODUCT DEVELOPMENT AND  
COLLABORATION AGREEMENT by and between Rising Pharmaceuticals, Inc.  
("Rising") and SigmaPharm Laboratories, LLC ("SigmaPharm"), dated as of  
June 22, 2006 (the "Agreement")**

**WHEREAS**, Rising and SigmaPharm wish to clarify the Agreement by amending certain provisions of the Agreement.

NOW, THEREFORE, in consideration of the mutual promises contained in this Amendment, and their continued performance under the Agreement, Rising and SigmaPharm agree as follows:

- 1) Section 1.43 of the Agreement is amended to substitute the phrase "Metropolitan Statistical Area" for the phrase "Standard Metropolitan Statistical Area."
- 2) THIS PARAGRAPH LEFT INTENTIONALLY BLANK.
- 3) Section 1.52 of the Agreement is deleted and replaced in its entirety by the following:

**1.52 "Rising's Fee"** shall be calculated on a per Product basis as follows: (i) a distribution fee for the Product which shall include distribution, shipping, warehousing, rebate and chargeback management, accounting, customer service, and inventory financing (where applicable) expenses and shall be equal to the following: in the event that annual Net Sales of all Products under all Product Schedules are less than \$10 Million, four percent (4%) of the annual Net Sales of the subject Product; in the event that annual Net Sales of all Products under all Product Schedules are greater than \$10 Million but less than \$20 Million, three point five percent (3.5%) of the annual Net Sales of the subject Product; in the event that annual Net Sales of all Products under all Product Schedules are greater than \$20 Million but less than \$30 Million, three (3%) of the annual Net Sales of the subject Product; in the event that annual Net Sales of all Products under all Product Schedules are greater than \$30 Million but less than \$50 Million, two point five percent (2.5%) of the annual Net Sales of the subject Product; in the event that annual Net Sales of all Products under all Product Schedules are greater than \$50 Million but less than \$100 Million, two percent (2%) of the annual Net Sales of the subject Product; and in the event that annual Net Sales of all Products under all Product Schedules are greater than \$100 Million, one point five percent (1.5%) of the annual Net Sales of the subject Product; plus (ii) a marketing and sales fee for the Product which shall include travel, tradeshow and other sales-related expenses, sales administration, and sales incentives and shall be equal to the following: in the event that annual Net Sales of all Products under all Product Schedules are less than \$10 Million, four percent (4%) of the annual Net Sales of the

*RY*  
9/4/08

*[Signature]*  
9/4/08

subject Product; in the event that annual Net Sales of all Products under all Product Schedules are greater than \$10 Million but less than \$20 Million, three point five percent (3.5%) of the annual Net Sales of the subject Product; in the event that annual Net Sales of all Products under all Product Schedules are greater than \$20 Million but less than \$30 Million, three (3%) of the annual Net Sales of the subject Product; in the event that annual Net Sales of the all Products under all Product Schedules are greater than \$30 Million but less than \$50 Million, two point five percent (2.5%) of the annual Net Sales of the subject Product; in the event that annual Net Sales of all Products under all Product Schedules are greater than \$50 Million but less than \$100 Million, two percent (2.%) of the annual Net Sales of the subject Product; and in the event that annual Net Sales of all Products under all Product Schedules are greater than \$100 Million, one point five percent (1.5%) of the annual Net Sales of the subject Product.

The Rising Fee used for each Product for the calculation of Net Profits for the first three Calendar Quarters of a calendar year shall be based upon Rising's estimate, subject to SigmaPharm consent which shall not be unreasonably withheld, of annual Net Sales for all Products under all Product Schedules for that calendar year. If, at the end of the calendar year, it is discovered that Rising's estimate of annual Net Sales for all Products under all Product Schedules was not correct, the appropriate adjustment will be made in the distribution of Net Profits pursuant to Section 8.3 of the Agreement following the 4<sup>th</sup> Quarter of that calendar year. As used in this Section 1.56, the term "calendar year" means the period starting on January 1 of a year and ending on December 31 of that same year.

4) The terms "Schedule," "Product Schedule," and "Specimen Schedule" in the Agreement (including any Amendment to the Agreement) have the same meaning unless specifically indicated otherwise in the Agreement or the Amendment.

5) The last sentence of Section 14.10 is deleted and replaced in its entirety by the following:

If there is a conflict between the provisions of this Agreement and the provisions of a Product Schedule, the provisions of the Product Schedule shall control and be determinative for the Product which is identified and described in that Schedule.

6) Section 14.13 of the Agreement is deleted and replaced in its entirety by the following:

**14.13. Survival.** All representations, warranties, covenants, and promises of the Parties and the terms and conditions of Sections 8, 10, 12, 13, and 14, including all subsections of


those Sections, shall survive the termination of a Product Schedule and/or this Agreement, notwithstanding any language in the Agreement or a specific Product Schedule to the contrary.

- 7) This Amendment applies to all Products listed on any Schedule to the Agreement and shall be effective as to all Products as of the Effective Date.
- 8) Capitalized terms used in this Amendment have the same meaning as given those terms in the Agreement.
- 9) Except as expressly modified by this Amendment, the Agreement is not changed in any respect by this Amendment.
- 10) The Effective Date of this Amendment is September 4, 2008.

IN WITNESS WHEREOF, Rising and SigmaPharm, by and through their duly authorized representatives, have signed this Amendment intending to be fully bound.

Rising Pharmaceuticals, Inc.

SigmaPharm Laboratories, LLC

By: 

By: 

Name: RONALD GOLD

Name: SPIRO SPIREAS, Ph.D.

Title: President

Title: CHAIRMAN & CEO

Date: Sept. 4<sup>th</sup> 2008

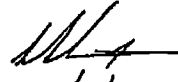
Date: Sept. 4, 2008

# EXHIBIT “2”

RISING PHARMACEUTICALS, INC.  
3A Pearl Court  
Allendale, New Jersey 07401

December 20, 2010

SigmaPharm Laboratories, LLC  
~~860 Town Center Drive~~ 3375 PROGRESS DR.  
~~Langhorne, PA 19047~~ BENSALEM, PA 19020

  
1/6/11

**Re: Agreement with Rising Pharmaceuticals, Inc.**

Dear SigmaPharm Laboratories, LLC,

Rising Pharmaceuticals, Inc. ("RP") has entered into a definitive agreement under which Sun Acquisition Corp., a wholly owned subsidiary of Aceto Corporation, will acquire substantially all of the assets of RP (the "Transaction"). Sun Acquisition Corp., which will change its name to Rising Pharmaceuticals, Inc. upon the closing of the Transaction (the "Closing"), is referred to herein as "New Rising". We have agreed to assign to New Rising, and New Rising has agreed to assume from RP, the agreement, dated February 2, 2006, between you and RP (the "Agreement"), effective as of the Closing. We will inform you of the date of the Closing, which is anticipated to be prior to December 31, 2010.

I am excited about the opportunity this represents for our business. Both David Rosen and I plan to maintain key roles in the management of the business after the Closing (as New Rising Employees), and we anticipate that substantially all of RP's other current employees will be hired by New Rising. Accordingly, we don't anticipate that our working relationship with your company will change significantly, if at all, after the Closing.

New Rising's assumption of our obligations under the Agreement is conditioned upon your granting your consent to such assumption, which consent you grant by your signature below, with effect from and after the Closing only.

Your obligations under the assigned Agreement will remain unchanged, except that they will be in favor of New Rising rather than RP. Similarly, any obligations to you arising after the Closing under the assigned Agreement will remain unchanged, except that they will be the responsibility of New Rising rather than RP.

As such, any legal notices or similar communications after the Closing should be directed to:

Rising Pharmaceuticals, Inc  
3A Pearl Court  
Allendale, New Jersey 07401  
Fax: (201) 961-1234  
Attn: Steven S. Rogers

For your convenience, this letter agreement may be signed in counterparts, each of which shall constitute an original, but all of which shall constitute a single agreement. This letter agreement shall be governed by the law governing the Agreement without regard to conflict of law issues, and shall be binding upon the parties and their respective successors and assigns.

If you have any questions, please feel free to contact me at (201) 961-9000 or [rgold@risingpharma.com](mailto:rgold@risingpharma.com). Thank you very much.

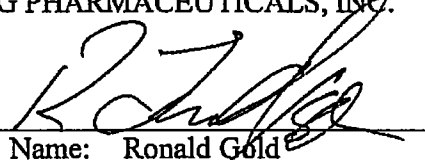
*[signature page follows]*

Please confirm your acknowledgement and agreement with the foregoing by signing and returning this letter agreement to the undersigned at the address listed at the beginning of this letter agreement.

Sincerely,

RISING PHARMACEUTICALS, INC.

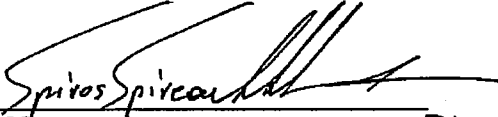
By:

  
Name: Ronald Gold  
Title: President and CEO

ACCEPTED AND AGREED:

SIGMAPHARM LABORATORIES, LLC

By:

  
Name: SPIRO SPIREAS, Ph.D.  
Title: CHAIRMAN & CEO  
Date: Jan. 6, 2011